



June 28, 2024

VIA Email

Howard L. Sollins, Esquire
Baker Donnelson
100 Light Street
Baltimore, Maryland, 21202

Re: SurgCenter at National Harbor, LLC
dba Harborside Surgery Center
Application for Certificate of Need to Convert a
Procedure Room to an Operating Room

Dear Mr. Sollins:

The Maryland Health Care Commission (Commission) staff has reviewed the above-referenced Certificate of Need (CON) application. Please provide responses to the following questions:

General

1) Provide a response for the following:

- A. On p. 12, clarify if this is a new health care facility, or a change in the type or scope of any health care service offered by a facility.
- B. The current hours and days of operation at Harborside Surgery Center.
- C. On p. 14, provide documentation or cite the source that supports the statements that “ambulatory surgery facilities are increasing becoming the site of choice by patients, payors, and surgeons for more complex cases...” and for the statement “increase patient satisfaction, decrease 30-day readmission rates, decrease infection rates, and decrease post-acute care stays in SNFs and rehabs.”
- D. Regarding the Project Budget (Attachment 4, Table E), provide the calculations used for the \$23,043 in Contingency Costs.
- E. Will Harborside keep procedure room 235 in service or take it out-of-service during the four weeks of renovations?
- F. Will the renovations to the procedure room include upgrades to meet ASHRAE operating room standards for ventilation systems?

Applicant History, Statement of Responsibility, Authorization and Release of Information, and Signature

- 2) Clarify the relationship of P. Marshall Maran, Managing Member, who signed the affirmation on p. 23 for the CON application. The table listing the Harborside ownership on p. 21 does not list P. Marshall Maran as an owner. Please include an ownership chart that shows all parties with a 5% ownership interest or greater in M2O.
- 3) More information is required regarding M2 Orthopedic Partners Holdings (M2O), LLC. Please provide:
 - A. What is M2O's level of expertise and its role in operating and/or owning ambulatory surgery facilities?
 - B. Please document the quality performance of each ambulatory surgery facility owned or operated by M2O.
 - C. List each of the other health care businesses and entities owned and/or operated by M2O.
- 4) What is Archimedes Health Investors, which is a private equity firm, and its relationship with M2O? Provide information on the size of Archimedes portfolio and the health care companies in its portfolio.
- 5) Is M2O incorporated within the State of Maryland? An organizational chart with the relationship between Harborside to both M2O and Archimedes Health Investors would be helpful.

State Health Plan

COMAR 10.24.01.08G(3)(a), The State Health Plan

General Surgical Services COMAR 10.24.11

Information Regarding Charges and Network Participation 05A(1)

- 6) Respond to the following:



- A. Regarding Subsections .05A(1)(a), (b), and (c), will Harborside provide a representative list of the charges for surgical services on its website and will Harborside post the health carrier networks in which Harborside and its physicians participates on its website? If not, please explain why not.
- B. Regarding Attachment 5, please provide:
- 1) a complete copy of the brochure that Harborside gives to its patients that shows Harborside's charity care and financial assistance policy.
 - 2) Please show where in this brochure there is language regarding the provision of Harborside providing out-of-pocket charges to patients prior to arrival at the surgery center.
 - 3) Is this policy for out-of-pocket charges to patients on Harborside's website?

Charity Care and Financial Assistance Policy 05A(3)

- 7) Regarding Harborside's response to Regulation .05A(3)(a) and Attachment 6, Charity Care and Financial Assistance Policy, please update this policy to provide the steps used by Harborside's staff to make a determination of probable eligibility¹ for charity care and financial assistance within two business days and the steps in notifying the patient of that determination.

A determination of probable eligibility should only require the minimum amount of information needed by Harborside regarding whether the patient is eligible for charity care and financial assistance for the surgical services proposed by Harborside. This step would require such minimal information as an individual's annual salary or copies of the patient's most recent paychecks, the number of members in family, a patient's successful application for a determination of medical assistance or financial assistance for health care services, and/or any other information that would assist the Harborside business office or surgical coordinator in the determination of probable eligibility for charity care and financial assistance.

A final determination of financial assistance may require the patient to submit a separate and completed financial assistance application with all the financial information necessary for Harborside to determine whether the patient will receive charity care and financial assistance for surgical services offered by Harborside. Please revise and update

¹ There is a difference in the determination of probable eligibility versus a final determination of financial eligibility for charity care and financial assistance.



Harborside's policy in Attachment 6 for making a final determination of probable eligibility for financial assistance.

A determination of probable eligibility should only require the minimum amount of information needed by Harborside regarding whether the patient is eligible for charity care and financial assistance for the surgical services proposed by Harborside. This step would require such minimal information as an individual's annual salary or copies of the patient's most recent paychecks, the number of members in family, a patient's successful application for a determination of medical assistance or financial assistance for health care services, and/or any other information that would assist the Harborside business office or surgical coordinator in the determination of probable eligibility for charity care and financial assistance.

A final determination of financial assistance may require the patient to submit a separate and completed financial assistance application with all the financial information necessary for Harborside to determine whether the patient will receive charity care and financial assistance for surgical services offered by Harborside. Please revise and update Harborside's policy in Attachment 6 for making a final determination of probable eligibility for financial assistance.

- 8) Please provide a copy of the financial assistance application form that the patient must complete to receive a final determination of charity care and financial assistance.
- 9) Regarding Attachment 6, under Eligibility Criteria, please clarify the meaning of "current poverty level" or "federal poverty guideline". Revise Harborside's policy to indicate that the sliding fee scale identified in this policy will utilize the current federal poverty guidelines in determining eligibility for charity care and financial assistance, such as at: <https://aspe.hhs.gov/topics/poverty-economic-mobility/poverty-guidelines>.
- 10) Regarding Harborside's response to Regulation .05A3(b) and Attachment 6, please show:
 - A. Where on Harborside's website the policy on charity care and financial assistance is posted?
 - B. What other modes of communication Harborside will use to notify the public and patients of its charity care and financial assistance policy? Examples could be publication in local newspapers, public service announcement, inclusion in the



Harborside patient brochure (Attachment 5), or notification to the Prince George's County Department of Health and other local health agencies and providers.

- C. Regarding Harborside's response to Regulation .05A(3)(f) and Attachment 6, please show the average amount of charity services provided by other Maryland ambulatory surgery facilities in the most recent year reported in comparison to Harborside.

11) Provide a response to the following:

- A. Regarding Harborside's response to Attachment 6 (paragraph 8.b) on p. 28, please provide further discussion as to how Harborside will meet its Charity Care Goals annually.

12) The applicant indicates in Table 3, Revenues and Expenses – Entire Facility on p. 66-67 that the Patient Mix as a Percent of Total Revenue will include 0.0% Medicaid and 0.0% Self Pay. The table also shows the breakdown in revenue reimbursement for Harborside by either Medicare, Blue Cross, Commercial Insurance, or other payers (i.e., worker's compensation and Veteran's Administration).

- A. Explain how Harborside will meet its annual charity care goal (defined by the applicant as one percent of total operating expenses, p. 30) if the patient mix does not include Medicaid and self-pay patients?
- B. The applicant indicates in its response to Regulation .05A1(b) above (see page 25 of the application), that Medicaid is not included in the list of current health carrier networks under contract ².

13) Please provide the historical level of charity care provided by Harborside for the years 2022 through year-to-date 2024. If not able to provide this information, then explain why Harborside cannot report the historical amount of charity care provided.

Attachment 6

² MHCC does not recognize "bad debt" or "uncollected funds for services provided" as meeting the definition of charitable care.



- 14) Provide a copy of Harborside's Charity Care and Financial Assistance Policy in Spanish and show where this is posted on its website. Please state if this is also posted in all offices.

Quality of Care 05A(4)

- 15) With regard to M2O, provide a response to Regulation .05A(4)(e) for the following:

- A. As an applicant or a related entity that currently or previously has operated or owned one or more ASCs or ambulatory surgical facilities in or outside of Maryland in the five years prior to the applicant's filing of an application to establish an ambulatory surgical facility, shall provide details regarding the quality of care provided at each such ASC or ambulatory surgical facility including information on licensure, accreditation, performance metrics, and other relevant information.

Transfer Agreement 05A(5)

- 16) Provide a response for the following:

- A. Regarding Attachment 14, Harborside only has a transfer agreement with Inova Mount Vernon Hospital. Discuss why Harborside does not have a transfer agreement with an acute care hospital located in Maryland.
- B. Please explain whether Harborside discusses with patients and/or families before providing surgical services that the patient may be transferred to Inova Mount Vernon Hospital, especially for patients who are residents of Maryland.
- C. Discuss whether Harborside has a contingency plan if the facility is not able to arrange transportation due to traffic complications, or that the patient and/or family prefers a transfer to an acute care hospital in Maryland.

Need – Minimum Utilization for Establishment of a New or Replacement Facility 05B(2)

- 17) Provide the Excel spreadsheet with the calculations for OR need included for Table 6 on p. 41, Table 7 on p. 42, and Table 8 on 43. Cite the source for the surgical cases and surgical minutes in these three tables.

Design Requirements 05B(4)

- 18) Please have Harborside's architect attest that the design and construction for the third sterile operating room will comply with the latest FGI Guidelines.

Support Services 05B(5)

- 19) Provide a response as to how Harborside will provide pathology services for its patients.



Impact 05B(9)

20) Provide a response for the following:

A. For the 19 physicians listed in Table 11 & 12, pp. 52-53,

- 1) Provide the surgical specialty for each physician.
- 2) Clarify whether the reported surgical case volumes are for a calendar or fiscal year.
- 3) Clarify whether the surgical case volumes reported in Tables 11 and 12 and in Attachment 17 are for surgical cases performed in operating rooms only.
 - a) If these tables also include volumes for surgical cases performed in procedures rooms, please resubmit these two tables and Attachment 17 to report surgical cases performed in the operating rooms only.
- 4) Please cite the source for the projected surgical volumes reported in Attachment 17.
- 5) For Tables 11, 12 and Attachment 17, please clarify whether the utilization volumes are for (a) a 12-month period, (b) prorated for a twelve-month period (start of operations at Harborside's new location at National Harbor was February 17, 2023), or (c) from February through December 2023.
- 6) Based on the response to the previous question, discuss how the Historical 2023 volumes were used to calculate the projected surgical case volumes for the years 2024 through 2028.
- 7) In comparing the total historical and projected surgical cases reported in Tables 11 and 12 with Attachment 17, these projected total surgical case volumes do not agree. Please resolve any discrepancies in surgical cases reported between these two tables and Attachment 17.
- 8) Regarding Table 14 on pp. 55-56, please cite the source for the projected number of surgical cases at Harborside that were shifted from other surgical facilities.
- 9) Clarify the use of "HOPD" associated with Alexandria and Mount Vernon HOPD; does this represent the Inova hospitals located at these two locations?
- 10) Regarding Regulation .04B(9)(b), provide a response that addresses the impact of shifting surgical case volumes from Inova Alexandria Hospital and Inova Mount Vernon Hospital to Harborside. Will these shifted surgical cases account for 18 percent or more of the operating room time in use at these two hospitals?



Other Criteria

Alternatives to the Project G3(c)

21) Regarding the alternative where there is no conversion of the procedure room, and instead an addition of a third OR- please provide further discussion as to where the addition of a new operating room would be located in the current layout of the surgery center, the total estimated project cost for adding a third OR, and the projected amount of time needed to construct this additional third OR.

Project Financial Feasibility G3(d)

22) Regarding Table 3, Revenues and Expenses – Entire Facility, please discuss the basis for the loss of about \$744,000 in Net Income reported for the year 2022.

23) Regarding Attachment 22, Table L, Workforce Information, discuss:

- A. How Harborside will recruit 8.0 FTEs in Direct Care staff without negatively impacting staffing at existing hospitals and ambulatory surgical facilities in its service area?
- B. Why were no additional anesthetists added to the staff for the third OR? Are all anesthetists part of the medical staff, or do you also use certified registered nurse anesthetists (CRNAs)?

Project Impact G3(f)

24) Provide a response that addresses the impact of shifting surgical case volumes from existing hospitals and ambulatory surgical facilities located in Virginia, as indicated in Table 14, pp. 55-56 of the CON application.

Health Equity G3(g)

25) Harborside needs to address the health care disparities in availability, accessibility, and quality of care among different populations within its service area. As stated in the criterion, provide a response that addresses questions A-C regarding the following:



- A. With health equity in mind, the applicant shall identify the specific medically underserved area(s)/group(s)³ within the designated service area and outline how the proposed project will address the unique health needs and quality of care for each identified group.
- B. Applicants are expected to furnish a detailed overview of their organization's expertise and experience in health care access and service delivery. Emphasis should be placed on highlighting any relevant background that underscores the organization's commitment to equitable health care. This encompasses efforts to integrate implicit bias and cultural competency training within the health facility and among current staff members.
- C. Please provide a comprehensive account of how the applicant planned with the community during the preparations for this project and how it will continue to engage with the community. Include a description of any specific initiatives and programs aimed at improving community well-being that are relevant to the proposed project. If applicable, the applicant should acknowledge any unintended barriers caused by the project that may have been identified through community discourse and propose proactive solutions to mitigate and rectify potential issues.
- D. Provide a copy of the policy that directs resources to address the issue of Health Equity at Harborside.
- E. Please discuss whether Harborside conducts an outreach program with the community aimed at improving the health and well-being of the population within Harborside's service area.

Character and Competence (G3(h))

26) Please address the following questions regarding character and competence:

³ According to HRSA, medically underserved populations and areas are identified as those which lack access to primary care services. These groups may face economic, cultural, or language barriers to health care. Some examples include: People experiencing homelessness, people who are low-income, people who are eligible for Medicaid, Native Americans and other historically disadvantaged populations of color, migrant farm workers, etc.

(<https://bh.w.hrsa.gov/workforce-shortage-areas/shortage-designation#mups>)



Howard L. Sollins

June 28, 2024

Page 10

- A. Discuss whether Harborside requires the physician and staff at Harborside to complete educational classes and training that address competency and quality in their interactions with both the patient and their families during the provision of health care surgical services.

- B. Is M2O involved in the ownership, development, or management of another health care facility? If so, please provide a complete list of its involvement.

Please submit four copies of the responses to the above questions and the requests for additional information within ten working days of receipt. Also submit the response electronically, in both Word and PDF format, to our CON mailbox at mhcc.confilings@maryland.gov If additional time is needed to prepare a response, please let me know at your earliest convenience.

As with the request itself, all information supplementing the request 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, please contact me at (410) 764-5982.

Sincerely,



Eric Baker, Program Manager

cc: Jeanne Marie Gawel, Acting CON Chief
Bill Chan, Program Manager
Ruby Potter, MHCC
Deann Dunn, MHCC
Wynee Hawk, Director Health Facilities Planning and Development
Nilesh Kalyanaraman, Deputy Secretary for Public Health Services
Caitin Tepe, AAG
Alexa Bertinelli, AAG
Mariama Gondo, Chief Outpatient Quality Initiatives
Dr. Mathew Levy, Health Officer, Prince George's County



Howard L. Sollins
June 28, 2024
Page 11

Michel Briggs, Office of Health Care Quality
Oksana Likhova, Office of Health Care Quality



mhcc.maryland.gov