MEMORANDUM

TO: Commissioners

FROM: Ewurama Shaw-Taylor
Chief, Certificate of Need

RE: Surgcenter at National Harbor, LLC
Certificate of Need for an Ambulatory Surgical Facility in
Prince George's County
Docket No. 24-16-2470

DATE: November 21, 2024

Surgcenter at National Harbor, LLC, d/b/a Harborside Surgery Center (Harborside) is an existing ambulatory surgery center (ASC-2)[1] that provides outpatient surgery procedures with two operating rooms (OR) and three procedure rooms located at 251 National Harbor Boulevard, Suite 200 in Oxon Hill, Prince George's County.

Project Description

Harborside seeks a Certificate of Need from the Maryland Health Care Commission to add one sterile OR to its existing center, resulting in three sterile ORs after project completion and thereby establishing an ambulatory surgical facility (ASF).[2] The applicant states that the project will renovate and convert an existing procedure room to an OR, resulting in a facility with three ORs and two procedure rooms.

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[1] COMAR 10.24.11.07B(2) defines an "ambulatory surgery center" (ASC) as any center, service, office, facility, or office of one or more health care practitioners, a group practice, or a non-rate-regulated center owned by a hospital that has no more than two operating rooms, that operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization, and that seeks reimbursement from payors for the provision of ambulatory surgical services. An ASC-2 is an ambulatory surgery center with two operating rooms.

[2] COMAR 10.24.11.07B(3) defines an ambulatory surgical facility as a health care facility that: (a) has three or more operating rooms; (b) operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization and (c) seeks reimbursement from payors as an ambulatory surgical facility.

The estimated capital cost to renovate existing space into a third OR is $247,985, to be paid for by the applicant in cash. Harborside states that the original facility was designed and built for three ORs, but only two were originally commissioned, with the third licensed as a procedure room. The existing procedure room to be converted was built to sterile OR standards and shares medical gas and HVAC equipment with the two existing sterile ORs.

Staff Recommendation

The relevant State Health Plan (SHP) chapter considered in the review of this project is COMAR 10.24.11, State Health Plan for Facilities and Services: General Surgical Services. Also considered are the general CON review criteria at COMAR 10.24.01.08G(3)(a) through (h).

Staff concludes that Harborside has complied with all applicable SHP standards in COMAR 10.24.11. Harborside's projected surgical case volume and OR surgical minutes support the need for the addition of a third operating room and the establishment of an ASF. Also, under the review criterion of COMAR 10.24.01.08G(3), staff concludes that Harborside's forecasts are credible, the project is financially viable, and that the project is a cost-effective option for delivering outpatient surgical services for physicians and residents within its service area. The project will have a positive impact on patient access and will not negatively impact the cost of outpatient surgery in the service area, nor will the project have a significant negative impact on existing providers of outpatient surgical services. Staff also concludes the applicant has appropriately responded to the criteria on Health Equity and Character and Competence.

Based on the conclusion that the proposed project complies with the applicable standards in COMAR 10.24.11, the General Surgical Services chapter of the State Health Plan, and with the Certificate of Need review criterion at COMAR 10.24.01.08G(3)(a)-(h), and as explained more fully in this Staff Report, Staff recommends the Maryland Health Care Commission find that applicant has met its burden and **APPROVE** Harborside s application for a Certificate of Need with the following conditions:

Prior to first use, Harborside shall provide to the public or patient, upon inquiry or as required by applicable regulations or law, information concerning charges for the full range of surgical services provided.

Prior to first use approval, Harborside shall ensure that it provides to the public, upon inquiry or as required by applicable law, the names of the health care carrier networks in which it and its surgeons currently participate.

Prior to first use approval, Harborside shall provide its plan to ensure that it provides charity care that is equivalent to or greater than the average amount of charity care provided by ASFs in the most recent year reported, measured as a percentage of total operating expenses, and that it reports charity care and bad debt as defined in the Freestanding Ambulatory Surgery Facility Survey.

Prior to first use approval, Harborside shall amend its brochure and website to include a link to the medical financial assistance and charity care policies.

Harborside will adopt a policy stating that annually, as part of the budgeting process, Harborside will include a discussion with its Board to discuss and identify necessary resources needed to address its commitment to Health Equity. Before first use, Harborside will identify the specific social determinants of health of their service area and submit a plan as to how this project plans to address it, including updated plans for the outreach clinic, and their discussions with Prince George's county department of health.

IN THE MATTER OF	*	**BEFORE THE**
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	*	
SURGCENTER AT NATIONAL	*	
HARBOR, LLC	*	**MARYLAND HEALTH**
	*	
d/b/a HARBORSIDE SURGERY	*	
CENTER	*	
	*	**CARE COMMISSION**
Docket No.: 24-16-2470	*	
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STAFF REPORT AND RECOMMENDATION

November 21, 2024

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I. INTRODUCTION

The Applicant

SurgCenter at National Harbor, LLC d/b/a Harborside Surgery Center (Harborside or applicant) is the subject of this review. Harborside is located at 251 National Harbor Boulevard, Suite 200 in Oxon Hill, Maryland (Prince George's County) and is currently licensed by the State of Maryland as an ambulatory surgery center with two operating rooms and three procedure rooms (ASC-2).[1] There are 20 staff surgeons at the center—18 orthopedic surgeons, one otolaryngologist (ENT) surgeon, and one general surgeon.

M2 Orthopedic Partners Holdings, LLC, (M2O) holds a 60.3 percent ownership share of Harborside. Fourteen physicians have minority ownership shares (less than five percent), with only one physician having greater than five percent ownership shares in Harborside. M2O manages another entity, Anderson Orthopaedic Clinic, which lists six Virginia locations on its website.[2] M2O is incorporated in the State of Delaware and is included in the portfolio of Archimedes Health Investors, a private equity firm focused on the healthcare industry. Appendix One provides an organizational chart illustrating the relationship between Harborside, M2O and Archimedes Health Investors.

The Project

A healthcare facility with three or more sterile operating rooms is defined as an ambulatory surgical facility (ASF).[3] Harborside proposes to convert one procedure room to an operating room, resulting in three sterile operating rooms and two procedure rooms after project completion, thereby establishing an ambulatory surgical facility. [4,5,6] The specific identified issues at the current location that have generated the need to expand Harborside include:

- The existing facility has experienced a 36 percent increase in total facility volume since its relocation to the National Harbor site in 2021;
- Total Joint Arthroplasty (TJAs) surgical procedures have experienced a 186 percent

[1] COMAR 10.24.11.07B(2) defines an "ambulatory surgery center" (ASC) as any center, service, office, facility, or office of one or more health care practitioners, a group practice, or a non-rate-regulated center owned by a hospital that has no more than two operating rooms, that operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization, and that seeks reimbursement from payors for the provision of ambulatory surgical services. An ASC-2 is an ambulatory surgery center with two operating rooms.
[2] https://andersonclinic.com/
[3] COMAR 10.24.11.07B(3) defines an ambulatory surgical facility as a health care facility that: (a) has three or more operating rooms; (b) operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization and (c) seeks reimbursement from payors as an ambulatory surgical facility.
[4] COMAR 10.24.11.07B(23) states an operating room or OR means a sterile room in the surgical suite that meets the requirements of a restricted area and is designated and equipped for performing surgical operations or other invasive procedures that require an aseptic field.
[5] COMAR 10.24.11.07B(30) states a "procedure room" means a non-sterile room in which minor surgical procedures are performed, with access from a semi-restricted corridor or an unrestricted corridor."
[6] COMAR 10.24.01.02A(2).

increase in procedure volume performed from 2022 to 2023, with approximately 1,200 annual procedures; and

- In 2023, the Centers for Medicare and Medicaid Services moved total shoulder arthroplasty from the inpatient only list to the ASC-Covered Procedures List (CPL) leading to increased volume of TJAs performed at Harborside. (DI #3, pp. 13-14).

The estimated project cost is $247,985 to convert an existing procedure room to an operating room. Harborside proposes to finance the project with cash. An itemized project budget follows in Table I-1. The applicant expects to begin renovation within two months after the Certificate of Need (CON) is approved, the proposed project is expected to be completed within four weeks after initiation of construction. (DI #3, p. 14 and, p. 18).

Table I-1: Estimated Uses and Sources of Funds
Replace Procedure Room with An Operating Room

Uses and Sources of Funds	
	Total
Land Purchase	$0
Subtotal	**$0**
Building	$115,217
Fixed Equipment	$0
Architectural, Engineering, Planning	$5,831
Permits	$3,894
Subtotal	**$124,942**
Contingency Allowance	$23,043
Previous Expenditures (Design/Planning/Etc.)	$0
Subtotal	**$23,043**
TOTAL CURRENT CAPITAL COSTS	**$147,985**
Inflation Allowance	$0
TOTAL CAPITAL COSTS	**$147,985**
Loan Placement Fees	$0
Application legal fees	$55,000
Other	$45,000
SUBTOTAL	***$100,000***
TOTAL USES OF FUNDS	***$247,985***
Cash	$247,985
Philanthropy (to date and expected)	$0
TOTAL SOURCES OF FUNDS	**$247,985**

Source: DI #3, att. 4, Table E.

Staff Recommendation

Staff recommends that the Maryland Health Care Commission (MHCC or Commission) approve this project based on staff's conclusion that the proposed project complies with the

COMAR 10.24.11, the General Surgical Services State Health Plans standards and criteria. The applicant has also demonstrated that the proposed ASF will be financially viable and a cost-effective option for delivering outpatient surgical services for residents within its service area. Further, staff concludes that the project will have a positive impact on patient access and will reduce the cost of outpatient surgery by facilitating increased utilization of the ASF setting over more expensive hospital outpatient departments and that it is not likely to have a negative impact on other outpatient surgical facilities. Staff also concludes that the applicant complies with the Health Equity and Character and Competence criterion.

Thus, as explained more fully in this Staff Report, staff recommends that the Commission issue a Certificate of Need (CON) for the proposed ASF based on the conclusion that the proposed project complies with the applicable standards in COMAR 10.24.11, the General Surgical Services State Health Plan (SHP) Chapter, and with the CON review criterion at COMAR 10.24.01.08G(3)(a)-(h). COMAR 10.24.11.05 (1)(c) requires the following condition:

> Prior to first use, Harborside shall provide to the public or patient, upon inquiry or as required by applicable regulations or law, information concerning charges for the full range of surgical services provided.

In addition, staff recommends the following conditions:

> Prior to first use approval, Harborside shall ensure that it provides to the public, upon inquiry or as required by applicable law, the names of the health care carrier networks in which it and its surgeons currently participate.

> Prior to first use approval, Harborside shall provide its plan to ensure that it provides charity care that is equivalent to or greater than the average amount of charity care provided by ASFs in the most recent year reported, measured as a percentage of total operating expenses, and that it reports charity care and bad debt, as defined in the Freestanding Ambulatory Surgery Facility Survey (FASF)[7].

> Prior to first use approval, Harborside shall amend its brochure and website to include a link to the medical financial assistance and charity care policies.

> Harborside will adopt a policy stating that annually, as part of the budgeting process, Harborside will include a discussion with its Board to discuss and identify necessary resources needed to address its commitment to Health Equity. Before first use, Harborside will identify the specific social determinants of health of their service area and submit a plan as to how this project plans to address it, including updated plans for the outreach clinic, and their discussions with Prince George's county department of health.

[7] COMAR 10.24.04.01A defines "Freestanding ambulatory surgical facilities" to mean facilities or offices which operate primarily for the purpose of providing surgical services to patients not requiring overnight hospitalization, and which are required to obtain a license under Health-General Article, §19-3B-02(a), Annotated Code of Maryland. COMAR 10.24.04.01B defines "Freestanding ambulatory surgical facilities survey" to mean any written request for data from the Maryland Health Resources Planning Commission to freestanding ambulatory surgical facilities.

II. PROCEDURAL HISTORY

Record of the Review

See Appendix 2, Record of the Review.

Interested Parties in the Review

There are no interested parties in the review.

Local Government Review and Comment

No comments were received from a local governmental body.

Community Support

No letters of community support were submitted on behalf of the applicant nor were any letters of community support received by the Commission.

III. STAFF REVIEW AND ANALYSIS

The State Health Plan

COMAR 10.24.01.08G(3)(a) — State Health Plan.

An application for a Certificate of Need shall be evaluated according to all relevant State Health Plan standards, policies, and criteria.

The relevant State Health Plan Chapter that will be considered in the review of this project is COMAR 10.24.11, General Surgical Services.

COMAR 10.24.11 - State Health Plan for Facilities and Services: General Surgical Services.

A. COMAR 10.24.11.05A — General Standards.

The following general standards reflect Commission expectations for the delivery of surgical services by all healthcare facilities in Maryland, as defined in Health-General §19-114(d). Each applicant that seeks a Certificate of Need for a project covered by this Chapter shall address and document its compliance with each of the following general standards as part of its application.

1. Information Regarding Charges and Network Participation. Information regarding charges for surgical services shall be available to the public.

(a) Each ambulatory surgery center, ambulatory surgical facility, and hospital shall provide to the public, upon inquiry or as required by applicable regulations or law, information concerning charges for the full range of surgical services provided.

(b) Each ambulatory surgery center, ambulatory surgical facility, and general hospital shall provide to the public, upon inquiry or as required by applicable regulations, the names of the health carrier networks in which it currently participates.

(c) Each ambulatory surgery center, ambulatory surgical facility, and general hospital shall provide to the public, upon inquiry, the names of the health carrier networks in which each surgeon and other health care practitioner that provides services at the facility currently participates.

(d) The Commission shall consider complaints to the Consumer Protection Division in the Office of the Attorney General of Maryland or to the Maryland Insurance Administration when evaluating an applicant's compliance with this standard in addition to evaluating other sources of information.

(e) Providing a patient with an estimate of out-of-pocket charges prior to arrival for surgery shall be a condition of any CON issued by the Commission.

Applicant Response

Harborside states it makes information regarding charges for the full range of surgical services available to the public upon inquiry. (DI #3, p. 24). While the Harborside website has a link to the patient rights and responsibilities document, it does not include a provision for inquiries about charges. Harborside stated that patients are provided with this information when scheduling their appointment. To comply with (a), applicant stated that prior to first use, it will post live links to the website with this information.[8] (DI #11, p.2).

For paragraphs (b) and (c), Harborside states that it will "provide to the public, upon inquiry or as required by applicable law, the names of the health care carrier networks in which it currently participates" and provide a list of its contracted carriers in the application (DI #3, p. 25). Further, applicant will "provide to the public, upon inquiry, the names of the health care carrier networks in which its employed surgeons and other employed health care practitioners currently participate." (DI #3, p. 25, DI #9, p.8).

In response to paragraph (d) Harborside indicates that it "is unaware of any complaints to the Consumer Protection Division in the Office of the Maryland Attorney General of Maryland or

[8] https://harborsidesurgcenter.com/for-patients/ accessed by staff on 9/10/2024.

to the Maryland Insurance Administration alleging that it failed to provide information either upon request or as required by law, to the public concerning its charges for the full range of surgical services." (DI #3, pp. 25-26).

Harborside states that it currently provides patients with an estimate of out-of-pocket charges at the time of scheduling and accepts that providing a patient with an estimate of out-of-pocket charges prior to arrival for surgery shall be a condition of CON approval for paragraph (e). (DI #3, p. 26).

Staff Analysis

Staff confirmed the response to COMAR 10.24.11.05A(1) and that the applicant will provide all the policies and information regarding charges. The applicant also stated it will provide both its and the surgeon's network participation as required by paragraphs (a) through (e) of this standard. Harborside maintains a charge list for all procedures and updates it periodically. A document version of this list is available to the public upon request. The applicant states that, in its CON application and on its website, it provides information regarding charges to all patients prior to surgery. Harborside plans to update its website prior to first use to include its network participation.

Additionally, the Consumer Protection Division in the Office of the Maryland Attorney General of Maryland and the Maryland Insurance Administration websites were reviewed and there were no findings. Staff recommends the Commission find that the applicant complies with this standard with the following conditions:

> Prior to first use, Harborside shall provide to the public or patient, upon inquiry or as required by applicable regulations or law, information concerning charges for the full range of surgical services provided.
>
> Prior to first use approval, Harborside shall ensure that it provides to the public, upon inquiry or as required by applicable law, the names of the health care carrier networks in which both it and its surgeons currently participates.

2. Information Regarding Procedure Volume. Each hospital, ambulatory surgical facility, and ambulatory surgery center shall provide to the public upon inquiry information concerning the volume of specific surgical procedures performed at the location. A hospital, ambulatory surgical facility, or ASC shall provide the requested information on surgical procedure volume for the most recent 12 months available, updated at least annually.

Applicant Response

Harborside states that upon request it will provide the public information concerning the volume of specific surgical procedures performed at Harborside for the most recent 12 months available and will update this information at least annually. (DI #3, p. 26).

Staff Analysis

Applicant has affirmatively stated its commitment to provide surgical procedure volumes to the public, upon request for a 12-month time frame. Staff concludes that the applicant complies with this standard.

3. Charity Care and Financial Assistance Policy. Each hospital and ambulatory surgical facility shall have a written policy for the provision of charity care and financial assistance regarding free and reduced-cost care to uninsured, underinsured, or indigent patients and shall provide ambulatory surgical services on a charitable basis to qualified persons consistent with the policy. The policy shall include, as applicable below, at a minimum:

(a) ***Determination of Eligibility for Charity Care or Financial Assistance.*** **Within two business days following a patient's request for charity care services, application for medical assistance, or both, the hospital or ambulatory surgical facility shall make a determination of probable eligibility and notify the patient of that determination.**

Applicant Response

Harborside provided a copy of its Medical Financial Assistance (MFA) program which states that "Within two business days of receipt of a patient's request for financial assistance or an application for medical assistance, Harborside's surgical coordinator will provide a determination of probable eligibility." (DI #3, p. 27).

(b) ***Notice of Charity Care and Financial Assistance Policy.*** **Public notice and information regarding the hospital or ambulatory surgical facility's charity care policy shall be disseminated, on an annual basis, through methods designed to best reach the facility's service area population in a format understandable by the service area population. Notices regarding the facility's charity care policy shall be posted in the registration area and business office of the facility. This notice shall include general information about who qualifies and how to obtain a copy of the policy or may include a posted copy of the policy. Prior to a patient's arrival for surgery, the facility shall address any financial concerns of the patient, and individual notice regarding the facility's charity care policy shall be provided.**

Applicant Response

Applicant indicates that the MFA policy will be posted on Harborside's website. Applicant submitted an update to its Charity Care and Financial Assistance Policy (DI #9, att. 33). The determination of probable eligibility is subject to change, based on the receipt of supporting documentation. (DI #9, p. 8 and att. 33).

Applicant states that, once the CON is approved, a copy of Charity Care and Financial Assistance Policy will be published annually. In addition, applicant will place information about

its Charity Care and Financial Assistance Policy, both in English and Spanish, on its website, and in provider offices within waiting rooms. It will also update its patient brochure (DI #11, p. 2 and att. 1). The applicant included an example of the proposed public notice, entitled Notice of Charity Care and Financial Assistance. (DI #3, p. 28, att. 8). The applicant also stated that the surgical coordinator, during a preoperative phone call, informs the patient of out-of-pocket costs, optional payment methods, and provides the business office contact if a payment plan is needed. The patient cost is derived by a business office specialist verifying with the provider the intended procedure to be performed and the associated CPT codes. The office submits the planned procedural codes to the insurance company medical office portal. The reply from insurance provides patient specific cost based on current benefit and deductible. This information is provided to the patient via phone call, email and/or postal mail based on patient preference. (DI #9, p. 10).

(c) ***Criteria for Eligibility.*** **A hospital shall comply with applicable State statutes and HSCRC regulations regarding financial assistance policies and charity care eligibility. A health maintenance organization, acting as both the insurer and provider of health care services for members, shall have a financial assistance policy for its members that is consistent with the minimum eligibility criteria for charity care required of ambulatory surgical facilities described in these regulations. An ambulatory surgical facility, at a minimum, shall include the following eligibility criteria in its charity care policies:**

(i) Persons with family income below 100 percent of the current federal poverty guideline who have no health insurance coverage and are not eligible for any public program providing coverage for medical expenses shall be eligible for services free of charge; and

(ii) Persons with family income above 100 percent of the federal poverty guideline but below 200 percent of the federal poverty guideline shall be eligible for services at a discounted charge, based on a sliding scale of discounts for family income bands.

Applicant Response

Regarding paragraph (c), applicant's policy states that financial assistance is provided "to persons who have health care needs and are uninsured, underinsured, ineligible for a government program, or otherwise unable to pay, for emergent and medically necessary care based on their financial situation." (DI #9, att. 33). The surgical scheduler will assist individuals in understanding what documentation is required to seek charity care at the facility. (DI #9 p. 3 of att. 33). The applicant's policy states they will utilize the following sliding scale for patients who meet the financial criteria. (DI #3, p. 27, DI #9, pp. 8-13 and att. 33).

1. A patient whose family income falls below 100 percent of the current poverty level, has no health insurance, and is not eligible for a public program providing for medical expenses will be eligible for services at no charge.

2. A patient whose family income exceeds 100 percent of the federal poverty guideline but is less than 200 percent of the federal poverty guideline will be eligible to receive

services at a discounted charge, based on a sliding scale of discounts determined by family income bands within the 100–200 percent range.

(d) A hospital with a level of charity care, defined as the percentage of total operating expenses that falls within the bottom quartile of all hospitals, as reported in the most recent HSCRC Community Benefit Report, shall demonstrate that its level of charity care is appropriate to the needs of its service area population.

Applicant Response

Paragraph (d) is not applicable.

(e) A hospital shall be able to demonstrate that its historic level of charity care or its projected level of charity care is appropriate to the needs of its actual or projected service area population. This demonstration shall include an analysis of the socio-economic conditions of the hospital's actual or projected service area population, a comparison of those conditions with those of Maryland's overall socio-economic indicators, and a comparative analysis of charity care provision by the applicant hospital and other hospitals in Maryland. The socio-economic indicators evaluated shall include median income and type of insurance by zip code area, when available. The analysis provided may also include an analysis of the social determinants of care affecting use of health care facilities and services and the health status of the actual or projected hospital service area population.

Applicant Response

Paragraph (e) is not applicable.

(f) An applicant submitting a proposal to establish or expand an ambulatory surgical facility for which third party reimbursement is available, shall commit to provide charitable surgical services to indigent patients that are equivalent to at least the average amount of charity care provided by ambulatory surgical facilities in the most recent year reported, measured as a percentage of total operating expenses. The applicant shall demonstrate that:

- **(i) Its track record in the provision of charitable health care facility services supports the credibility of its commitment;**
- **(ii) It has a specific plan for achieving the level of charitable care provision to which it is committed; and**
- **(iii) If an existing ambulatory surgical facility has not met the expected level of charity care for the two most recent years reported to the Commission, the applicant shall demonstrate that its historic level of charity care was appropriate to the needs of its service area population.**

Applicant Response

Harborside states that it cannot document that it has met the average percentage of charity care for ASFs requested in paragraph (f) because it has not tracked the provision of charity care, since becoming an ASC. In response to section (f)(iii), Harborside states it "is not an 'existing ambulatory surgical facility'", so this section of the standard did not apply. Harborside does state it commits to providing charity care to indigent patients at a level equal to one percent of total operating expenses. (DI #3, p. 30, DI #1a and DI #16., p. 1). The applicant also states that to achieve the targeted percentage of charitable care, they will review the Charity Care and Financial Assistance program developed at its quarterly Quality Assurance and Performance Improvement meetings to monitor the level of services provided.

(g) A health maintenance organization, acting as both the insurer and provider of health care services for members, if applying for a Certificate of Need for a surgical facility project, shall make a commitment to provide charitable services to indigent patients. Charitable services may be surgical or non-surgical and may include charitable programs that subsidize health plan coverage. At a minimum, the amount of charitable services provided as a percentage of total operating expenses for the health maintenance organization will be equivalent to the average amount of charity care provided statewide by ambulatory surgical facilities, measured as a percentage of total ambulatory surgical facility expenses, in the most recent year reported. The applicant shall demonstrate that:

(i) Its track record in the provision of charitable health care facility services supports the credibility of its commitment; and

(ii) It has a specific plan for achieving the level of charitable care provision to which it is committed.

(iii) If the health maintenance organization's track record is not consistent with the expected level for the population in the proposed service area, the applicant shall demonstrate that its historic level of charity care was appropriate to the needs of the population in the proposed service area.

Applicant Response

Paragraph (g) is not applicable.

Staff Analysis

The applicant has developed a charity care policy that meets the requirements in paragraphs (a) and (b) and (c) regarding financial assistance eligibility and notification requirements. The required website update has not been done at the time of this report. (accessed on 09/10/2024). Staff found that the only statement listed on this website under patient rights and responsibilities was that "Patients are responsible for assuring that the financial obligations for health care rendered are paid in a timely manner." The applicant does state that by First Use it will have this information posted online and easily visible to the public at its facility. (DI #3, p. 27, DI #9, p. 8 and p. 12).

The applicant questioned staff about the appropriate level of charity care provided in Prince

George's County during its pre-application conference. Staff provided an analysis of the County stating:

> An analysis of the 20745-zip code shows eight other ASCs all reporting $0 in charity care, except for one single-specialty outlier reporting $3,500 in charity care for 2022. If we expand out and look at the entire county, the pattern is similar. There are 36 other ASCs in the county and, other than the one mentioned above reporting $3500, only three others report some charity care ($1,000, $12,000, and $4,271) and the rest are all zero.

In addition to the staff analysis, the applicant reviewed the most recently completed ASF CON report for Chesapeake Eye Surgery Center in 2023. Chesapeake Eye Surgery Center located in adjacent Anne Arundel County agreed to provide charity care of one percent of operating expenses.[9] The applicant used this information to create its own benchmark for charity care at one percent of operating expenses. (DI #16, p. 1). Staff concludes that the applicant should easily be able to meet or exceed the average amount of charity care provided by ASFs as the standard requires.

Staff recommends the following conditions:

> Prior to first use approval, Harborside shall provide its plan to ensure that it provides charity care that is equivalent to or greater than the average amount of charity care provided by ASFs in the most recent year reported, measured as a percentage of total operating expenses, and that it reports charity care and bad debt as defined in the Freestanding Ambulatory Surgery Facility Survey.
>
> Prior to first use approval, Harborside shall amend its brochure and website to include a link to the medical financial assistance and charity care policies.

4. Quality of Care. A facility providing surgical services shall provide high quality care.

(a) An existing hospital or ambulatory surgical facility shall document that it is licensed, in good standing, by the Maryland Department of Health.

Applicant Response

Paragraph (a) does not apply as applicant is not an existing hospital or ASF.

(b) A hospital shall document that it is accredited by the Joint Commission or other accreditation organization recognized by the Centers for Medicare and Medicaid and the Maryland Department of Health as acceptable for obtaining Medicare certification and Maryland licensure.

[9] Docket No. 22-02-2461 Chesapeake Eye Surgery Center, LLC, approved on April 20, 2023. https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/documents/2023_decisions/con_chesapeake_eye_2461_decision_20230420.pdf

Applicant Response

Paragraph (b) does not apply as applicant is not a hospital.

(c) An existing ambulatory surgical facility or ASC shall document that it is:

(i) In compliance with the conditions of participation of the Medicare and Medicaid programs;

(ii) Accredited by the Joint Commission, the Accreditation Association for Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgery Facilities, or another accreditation organization recognized by the Centers for Medicare and Medicaid Services as acceptable for obtaining Medicare certification; and

(iii) A provider of quality services, as demonstrated by its performance on publicly reported performance measures, including quality measures adopted by the Centers for Medicare and Medicaid Services. The applicant shall explain how its ambulatory surgical facility or each ASC, as applicable, compares on these quality measures to other facilities that provide the same type of specialized services in Maryland.

Applicant Response

As an existing ASC, the applicant submitted a copy of its license dated February 17, 2023, from the Maryland Department of Health. (DI #3 att. 9). The applicant also provided documentation that it is accredited by the Accreditation Association for Ambulatory Health Care (AAAHC) from March 26, 2023 through March 25, 2026 and states it will renew its accreditation when it expires. (DI #3, att. 11). To demonstrate compliance with the Centers for Medicare and Medicaid (CMS) conditions of participation, the applicant provided a letter from the Office of Health Care Quality dated July 28, 2023, indicating that it complied with Federal participation requirements for an ambulatory surgery center participating in the Medicare program (DI #3, att. 10 and 11). Harborside also states it is enrolled in the Hospital Outpatient Reporting Program that publishes results on the QualityNet website. The applicant submitted publicly reported data for the period, 1/01/2024 - 5/15/2024. The publicly reported data contained eight measures, and, for each measure, there were either no reportable events or the measure was not applicable. (DI #3, pp. 32-33, att. 12). The eight measures reported on are:

- Experiencing a burn prior to discharge
- Experiencing a fall in the ASC
- Wrong site, side, patient, procedure or implant
- Transfer to hospital on discharge
- Patients 50 to 75 receiving a colonoscopy screening without biopsy or polypectomy (not applicable)
- Patients 18 and older with improved visual function within 90 days of cataract survey (not applicable)
- Patients who had a temperature in the PACU
- Cataract surgery with unplanned anterior vitrectomy (not applicable).

(d) An applicant seeking to establish an ambulatory surgical facility shall:

(i) Demonstrate that the proposed facility will meet or exceed the minimum requirements for licensure in Maryland in the areas of administration, personnel, surgical services provision, anesthesia services provision, emergency services, hospitalization, pharmaceutical services, laboratory and radiologic services, medical records, and physical environment;

(ii) Agree that, within two years of initiating service at the facility, it will obtain accreditation by the Joint Commission, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities or another accreditation organization recognized by the Centers for Medicare and Medicaid Services as acceptable for obtaining Medicare certification and approved by the State of Maryland; and

(iii) Acknowledge in writing that, if the facility fails to obtain the accreditation in subparagraph (ii) on a timely basis, it shall voluntarily suspend operation of the facility.

Applicant Response

For paragraph (d) the applicant stated it is an existing ASC, and this standard was addressed in paragraph (c).

(e) 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.

Applicant Response

For paragraph (e) the applicant states that it currently meets or exceeds the minimum requirements for licensure in Maryland in the areas of administration, personnel, surgical services provision, anesthesia services provision, emergency services, hospitalization, pharmaceutical services, laboratory and radiologic services, medical records, and physical environment for an ASC. The applicant also states it will similarly meet or exceed the minimum requirements for an ASF if approved. The applicant began providing quality metrics in 2024. (DI #3, pp. 33-34).

Staff Analysis

Staff has reviewed documentation submitted that shows Harborside's license is in good standing, and it is accredited. Harborside only began reporting performance metrics in CY2024. To date, Harborside has no quality complaints. Staff checked the quality reporting center website

to confirm data were submitted.[10] Staff confirmed the applicant has not operated any ASC or ASF other than Harborside in or outside of Maryland. Based on this limited documentation, the applicant provides quality care in its facility.

Staff concludes the applicant complies with this standard.

5. Transfer Agreements.

(a) Each hospital shall have arrangements for transfer of surgical patients to another hospital that comply with the requirements of Health-General Article §19-308.2.

(b) Each ambulatory surgical facility shall have a process for assuring the emergency transfer of surgical patients to a hospital that complies with the requirements of COMAR 10.05.05.09.

Applicant's Response

Paragraph (a) is not applicable because the applicant is not a hospital. For paragraph (b) Harborside submitted its transfer policy entitled Transfer From Surgery Center to Acute Care Hospital (DI #3, att. 13). It also supplied its existing transfer and referral agreement with Inova Mt. Vernon Hospital (DI #3, att. 14). The applicant stated that patients are informed by their surgeons that if they require a higher level of care than can be provided at the center, they will be transferred to Inova Mount Vernon Hospital or, if medically unstable, to the closest hospital. A medically unstable patient would be transported via ambulance and a call to 911. (DI #9, pp. 15-16, att.13, p. 2).

Staff Analysis

Staff reviewed the submitted transfer policy and transfer agreement. Given the transfer agreement was with a non-Maryland hospital, staff followed up with the applicant and questioned if patients were made aware they may be transported to a hospital outside of Maryland. The applicant stated that patients are informed prior to surgery that they will go to Inova Mount Vernon Hospital or in the case of an emergency to the closest hospital in Maryland or Virginia that is accepting emergency admissions.

Staff concludes that applicant complies with the standard.

COMAR 10.24.11.05B — Project Review Standards.

The standards in this regulation govern reviews of Certificate of Need applications involving surgical facilities and services. An applicant for a Certificate of Need shall demonstrate consistency with all applicable review standards.

[10] https://www.qualityreportingcenter.com/en/ascqr-program/data-dashboard/ccn/

(1) Service Area. An applicant proposing to establish a hospital providing surgical services or an ambulatory surgical facility shall identify its projected service area. An applicant proposing to expand the number of operating rooms at an existing hospital or ambulatory surgical facility shall document its existing service area, based on the origin of patients served.

Applicant Response

Harborside states that its existing service area encompasses Virginia, Maryland, and the District of Columbia. It provided patient origin data for the 12-month period from May 2023 to May 2024 that shows that patients residing in 126 zip Codes, located within 22 counties and the District of Columbia. Six counties and the District of Columbia accounted for over 85 percent of Harborside cases. The total number of patients for the 12-month period was 3,050 and include surgeries and other OR procedures. Table III-1 presents the summary data for the top region. (DI #3, pp. 35-37).

Table III-1, 2023-2024 Harborside Patient Origin in the Top Seven Jurisdictions Served

State	County	Total	Percent	Cumulative Percent
VA	Fairfax	1,321	43.97%	43.97%
VA	Arlington	269	8.95%	52.93%
VA	Alexandria	199	6.62%	59.55%
VA	Prince William	196	6.52%	66.08%
MD	Prince Georges	164	5.46%	71.54%
MD	Charles	86	2.86%	74.40%
DC	District of Columbia	68	2.26%	76.66%
Total	**Service Area**	**2,634**	**87.68%**	**87.68%**
VA		2,210	73.57%	73.57%
MD		356	11.85%	85.42%
DC		68	2.26%	2.26%
Total	**Service Area**	**2,634**	**87.68%**	**87.68%**

Source: DI #3, p. 36. The 12 months period is from May to May, 2023-2024.

Table III-1 represents approximately that 75 percent of patients treated at Harborside during the 12-month period resided in zip codes within the seven counties in Virginia, Maryland, and the District of Columbia. Applicant notes that the majority of these patients (43.97 percent) resided in Fairfax County, Virginia and that, in general, nearly 75 percent of patients in the service area are from the Commonwealth of Virginia. (DI #3, pp. 36-8).

The applicant also provided service area demographic information. (DI #3, att. 16). The data show population growth in the 65 and older age cohort. Applicant states that this demographic will need a broad range of orthopedic procedures that will support Harborside's projected growth as represented in Table III-2. (DI #3, p. 39-40).

Table III-2, Harborside Top Seven Jurisdiction's
Percent of Population Aged 65+ in CY 2024, CY 2029 and the Percent Increase by 2029

State	County	CY2024	CY2029	Increase in Age 65+ Population
VA	Fairfax	15.00%	17.20%	2.20%
VA	Arlington	11.50%	13.80%	2.30%
VA	Alexandria	14.20%	16.40%	2.20%
VA	Prince William	13.60%	16.00%	2.40%
MD	Prince George's	18.20%	20.90%	2.70%
MD	Charles	14.40%	17.50%	3.10%
DC	DC	13.00%	15.20%	2.20%
Service Area Jurisdictions Total		**14.70%**	**17.10%**	**2.40%**

Source: (DI #3, pg. 40, att. 16).

Staff Analysis

The applicant's defined service area for Harborside's surgical services includes zip codes primarily in Virginia. It also includes Washington DC and Maryland. The applicant receives under 12 percent of its patients from Maryland counties. The applicant bases this service area on where 87 percent of the surgical cases performed at Harborside originated in 2024. It also provided an analysis of the demographic changes projected to occur among the 65+ population cohort. The population aged 65+ for the top seven jurisdictions is projected to increase by 2.4 percent by 2029. The overall cumulative annual growth rate (CAGR)[11] from CY 2024 through CY 2029 is 3.3 percent for this population. Staff concludes this population has a high need for orthopedic surgery from degenerative joint conditions like osteoarthritis, which often necessitates surgical interventions like hip or knee replacements due to the natural wear and tear on their joints over time.

Staff concludes that the applicant complies with this standard.

(2) Need – Minimum Utilization for Establishment of a New or Replacement Facility. An applicant proposing to establish or replace a hospital or ambulatory surgical facility shall:

(a) Demonstrate the need for the number of operating rooms proposed for the facility, consistent with the operating room capacity assumptions and other guidance included in Regulation .06 of this Chapter.

(b) Provide a needs assessment demonstrating that each proposed operating room is likely to be utilized at optimal capacity or higher levels within three years of the initiation of surgical services at the proposed facility, consistent with Regulation .06 of this Chapter.

(c) An applicant proposing to establish or replace a hospital shall submit a needs assessment that includes:

(i) Historic trends in the use of surgical facilities for inpatient and outpatient surgical procedures by the new or replacement hospital's likely service area population;

[11] CAGR = (Ending Value / Previous Value) ^ (1 / # of periods) -1

(ii) The operating room time required for surgical cases projected at the proposed new or replacement hospital by surgical specialty or operating room category; and

(iii) In the case of a replacement hospital project involving relocation to a new site, an analysis of how surgical case volume is likely to change as a result of the relocation.

(d) An applicant proposing the establishment of a new ambulatory surgical facility shall submit a needs assessment that includes the following:

(i) Historic trends in the use of surgical facilities for outpatient surgical procedures by the proposed facility's likely service area population;

(ii) The operating room time required for surgical cases projected at the proposed facility by surgical specialty or, if approved by Commission staff, another set of categories; and

(iii) Documentation of the current surgical caseload of each physician likely to perform surgery at the proposed facility.

Applicant Response

The applicant references the data in Table III-3 as demonstrating need for the additional OR at the facility. They state that by the second full year after project implementation, the projected 2026 volume supports the need for three operating rooms based on total OR hours. (DI #3, p. 40, att. 17).

For the needs assessment in paragraph (b), applicant states that the proposed additional operating room will be identical to the two existing operating rooms in functionality and basic equipment. The applicant projects by analysis of surgical cases and minutes, that there is need for the increased capacity a third OR will provide. The applicant provided Table III-3 which shows four years of projected volume and demonstrates need for 1.03 ORs beginning in CY 2026 due to the volume increase. The need was also based on the estimates provided by physicians, which included cases and minutes. (DI #3, att. 17).

Table III-3, Harborside Actual and Projected OR Cases, Utilization and Need

	Actual Volume		Projected Volume				
	CY2022	**CY2023**	**CY2024**	**CY2025**	**CY2026**	**CY2027**	**CY2028**
Total Cases	1,151	1,846	2,145	2,376	2,676	2,959	3,032
Total Surgical Minutes in OR	99,327	159,164	186,130	208,038	235,989	262,558	269,935
OR Turnaround Minutes, 25 minutes per case	28,775	46,150	53,625	59,400	66,900	73,975	75,800
Total OR Minutes, including and Turnaround	128,102	205,314	239,755	267,438	302,889	336,533	345,735
Total Hours (minutes/60)	2,135.03	3,421.90	3,995.92	4,457.30	5,048.15	5,608.88	5,762.25
Optimal Capacity, Hours	1,632.00	3,264.00	3,264.00	4,896.00	4,896.00	4,896.00	4,896.00
Utilization, Percent	130.8%	104.8%	122.4%	91.0%	103.1%	114.6%	117.7%
OR Need (Total Hours/1632)	**1.3**	**2.1**	**2.4**	**2.7**	**3.1**	**3.4**	**3.5**

Source: DI #3, Table 6.

For paragraph (d) Harborside states it has been in continuous operation since 2012. In 2023, when it moved to the new facility at National Harbor, it added one operating room and one procedure room and is classified as an ASC-2 with two sterile ORs and three non-sterile procedure rooms. Harborside states the projected utilization after implementation of the proposed third operating room is primarily based on the anticipated case volume shift by Harborside surgeons from existing surgical facilities where they currently practice to Harborside. . The need was also based on the estimates provided by physicians, which included cases and minutes. (DI #3, att. 17).The baseline of surgical cases in Table III-4 consists of Harborside surgeons current year case volumes.

Table III-4 Source of Harborside Projected Surgical Cases

	Projected Volume				
	CY2024	CY2025	CY2026	CY2027	CY2028
Total Surgical Cases	2,145	2,367	2,676	2,989	3,032
Volume Shift from Other Facilities (From Baseline of 2,145)		231	531	814	887
Case Increase from Previous Year		222	309	313	43

Source: (DI #3, p. 44, Table 9).

The applicant states that the increase in cases will be accounted for by the shift of patients primarily from facilities outside of Maryland. The shift in cases by the current Harborside surgeons will mainly be from the three providers below:

- Inova Alexandria Hospital Outpatient Surgery
- Inova Mount Vernon Outpatient Surgery
- Inova Healthplex Franconia Springfield (DI #3, p. 44).

The applicant states that each of the 19 Harborside surgeons provided an individual physician submission. The submission includes the top five procedure codes and associated volumes of projected cases and the facilities from which it is anticipated that cases will be shifted to Harborside. (DI #3, p. 209-228, att. 17). This information indicates substantial practice growth. The applicant states that the impact of the potential shifts on the other area outpatient surgery settings will also be mitigated by the demographic growth in the population age 65+. (DI #3, pp. 43-45, and Table III-2, *supra, p. 16).*

Staff Analysis

A single dedicated outpatient general purpose operating room (OR) is at full capacity with utilization of 2,040 hours per year and optimal capacity of 80 percent of the full capacity which is 1,632 hours per year including surgical and turnaround time. COMAR 10.24.11.06 (A) (1) (b) (ii) and (iii). Harborside has been operating as a one OR ambulatory surgery center (ASC-1) through CY 2022, transitioning to two OR (ASC-2) in CY 2023. The CON application shows that Harborside had utilization of 130.8 percent and 104.8 percent with respect to optimal capacity in CY 2022 and CY 2023 respectively. (DI #3 p. 41 Table 6). The utilization numbers for CY 2022 and CY 2023 assume a turnover time of 25 mins per case. Utilization corresponds directly with OR need; when measured over 1,632 hours it yields 1.3 and 2.1 at optimal capacity for CY 2022 and CY 2023 respectively.

Further, staff conducted a 4-year retrospective analysis of the Commission's annual survey of ambulatory surgical facilities and ASCs[12] in Maryland (FASF Survey Analysis) involving CY 2018, CY 2019, CY 2021 and CY 2022 data which shows Harborside operated the facility at 115.2 percent, 118.9 percent, 110.2 percent and 111.8 percent of the optimal capacity in the four years respectively. (Appendix 5). COVID pandemic year CY 2020 data could not be collected, CY 2022 data showed discrepancy compared to CON and CY 2023 survey data was not available at the time of this report. Despite the discrepancy with CY 2022 data which applicant clarified in completeness response (DI #11, page 6), these analyses support the premise that Harborside operated the facility at or above optimal capacity through the end of CY 2022.

Harborside's utilization projections (CY 2024 through CY 2028, with CY 2023 as the base year) show the projected utilization (104.8%, 122.4%, 91.9%, 103.9%, 115.4%, 118.5%) which corresponds to OR need of 2.1, 2.4, 2.8, 3.1, 3.5 and 3.6 from CY 2023 through CY 2028 respectively (Appendix 5). This demonstrates the need for three operating rooms at Harborside in future.

Harborside demonstrates that by the second full year after implementation of the proposed OR, projected volumes would be 5,088.75 hours yielding a utilization of 103.9 percent. The projected utilization is based on the existing case volumes across the facility and that the proposed additional OR will be identical to the two existing ORs in functionality and basic equipment, sharing one-third of the case volume. The total projected case volume in the proposed OR is 803, 903, 998, 1022 from CY 2025 through CY 2028 respectively. The overall CAGR from CY 2023 through CY 2028 for the total cases at the facility and proposed OR is 10.7 percent.

[12] https://mhcc.maryland.gov/public_use_files/amsurgdownload.html

Paragraph (c) is not applicable.

Regarding paragraph (d), Harborside's service area lies within Virginia, Maryland and the District of Columbia. Currently, 75 percent or more of its cases in the rolling 12 months ending May 2024 were from seven regions: four counties in Virginia, two counties in Maryland and the District of Columbia. The Maryland service area contributed roughly 12 percent of the total cases (DI #3, p 35, Table 1). With respect to anticipated growth in overall population between 2024 and 2029, Harborside provided statistical population data from Claritas (DI #3 p 198-208 Attachment 15-16). The data highlights population growth for Harborside service area zip codes and age groups. The data shows that the 65+ age group is expected to grow faster than others. The CAGR from CY 2024 through CY 2028 for 65+ stands at 3.3 percent. Staff cross examined the Claritas population estimates with the U.S. Bureau of the Census data via the 2023 National Population Projections Tables: Main Series[13] and observed similar results. The five-year CAGR (CY 2025 through CY 2030) for 65+ stands at 2.4 percent.

Per CON (DI #3, Table 6 and 7) Harborside indicated the total minutes and turnaround time both at the facility level and proposed OR. The definition of optimal capacity includes surgical and turnaround time. Harborside assumes the turnaround time to be 25 minutes, which is the assumption time set forth in the regulations in absence of reliable information on turnaround time. (DI #3, pp. 41-42). With the assumed '*Turnaround Time'* per case' and the sum of '*Total Surgical Minutes in OR*' staff derived the '*Total OR Minutes per Case*' to be 98, 98, 100 and 96 minutes with a simple average of 98 minutes per case from CY 2018 through CY 2022 per the survey analysis (Appendix 5). With similar assumptions and data from CON the '*Total OR Minutes per Case*' yields 111, 111, 112, 112, 113, 113 and 114 minutes with a simple average of 112 minutes per case from CY 2022 through CY 2028 (Appendix 5). Staff observes that the increase in average time per case from 98 mins per the survey to 112 mins per the CON corresponds with two events; addition of an OR in 2023 (ASC-2 status) and the addition of a proposed OR in 2025 (ASF-3 status). Though the increase in Total OR Minutes per Case is evident from the analysis, staff does not have the required clinical expertise nor empirical data to correlate it with addition of an OR. While Harborside is in compliance with the data shared on operating room time, staff is unable to conclude the veracity of this data based on the historical trend analysis.

Lastly, per DI #19, Table 12 (revised), applicant indicated that starting CY 2025 there would be 20 physicians practicing at the facility who at the same time are empaneled with other ASC/ASFs as well other HOPDs within their existing service area. Applicant attached individual physician submissions in the original CON (DI #3 p 209-228 Attachment 17) that detailed the Top 5 Procedure Codes and associated volumes of cases for the 19 physicians then. Of the 19 physicians, 3 appear to be leaving the facility starting CY 2025. Of the 3, 2 did not have any volume of cases in CY 2023 and nor any in the projected years. The third physician did have cases from CY 2023 through CY 2028 (36, 15, 15, 15, 15 and 15). The addition of 4 new physicians starting CY 2025 is expected to overcome the volume of the departing physician (49, 49, 49, 49) from CY 2025 through CY 2028.

Apart from individual submissions, the physicians have demonstrated their continued support for Harborside by explicitly expressing and anticipating shifting of cases from their

[13] https://www.census.gov/data/tables/2023/demo/popproj/2023-summary-tables.html, Table 2

existing outpatient surgery settings. Updated projections from DI #19, Attachment 11 indicate growth in shifting of cases starting CY 2025 through CY 2028 (265, 566, 848, 922) which range from 11.0 percent of the total volume in CY 2025 (2,410) to 30.1% in CY 2028 (3,067). The increase in volume of cases with the addition of the 4 new physicians supports the reasonableness and consistency required for physician caseload at the proposed facility.

Staff concludes that the applicant complies with this standard.

(3) Need – Minimum Utilization for Expansion of An Existing Facility. An applicant proposing to expand the number of operating rooms at an existing hospital or ambulatory surgical facility shall:

(a) Demonstrate the need for each proposed additional operating room, utilizing the operating room capacity assumptions and other guidance included at Regulation .07 of this chapter;

Demonstrate that its existing operating rooms were utilized at optimal capacity in the most recent 12-month period for which data has been reported to the Health Services Cost Review Commission or to the Maryland Health Care Commission; and

(b) Provide a needs assessment demonstrating that each proposed operating room is likely to be utilized at optimal capacity or higher levels within three years of the completion of the additional operating room capacity, consistent with Regulation .06 of this chapter. The needs assessment shall include the following:

(i) Historic and projected trends in the demand for specific types of surgery among the population in the proposed service area;

(ii) Operating room time required for surgical cases historically provided at the facility by surgical specialty or operating room category; and

(iii) Projected cases to be performed in each proposed additional operating room.

This standard is not applicable, the applicant, an existing ASC (2 ORs or less) seeks to establish a new ASF (3 ORs or more) rather than expand an existing ASF.

(4) Design Requirements. Floor plans submitted by an applicant must be consistent with the current FGI Guidelines:

(a) A hospital shall meet the requirements in current Section 2.2 of the FGI Guidelines.

(b) An ambulatory surgical facility shall meet the requirements in current Section 3.7 of the FGI Guidelines.

(c) Design features of a hospital or ambulatory surgical facility that are at variance with the current FGI Guidelines shall be justified. The Commission may consider

the opinion of staff at the Facility Guidelines Institute, which publishes the FGI Guidelines, to help determine whether the proposed variance is acceptable.

Applicant Response

In response to the only applicable paragraph (b), Harborside submitted a letter from Misty Anguiano of the architectural firm Boulder Associates, Inc. confirming that the architectural design of the operating room suite at Harborside complies with Section 2.2 of the FGI Guideline. (DI #9, att. 35).

Staff Analysis

The applicant provided evidence of meeting the standard by submitting a letter from an architect from the firm Boulder Associates, Inc. stating that the operating room design complies with FGI guidelines.

Staff concludes that the applicant complies with this standard.

(5) Support Services. Each applicant seeking to establish or expand an ambulatory surgical facility shall provide or agree to provide laboratory, radiology, and pathology services as needed, either directly or through contractual agreements, in compliance with COMAR 10.05.05.

Applicant Response

Harborside states it has developed procedures to provide laboratory services for its patients through contractual agreement with Lab Corp and through Clinical Laboratory Improvement Amendments (CLIA) waived certification. Harborside staff are educated via annual competency on the safe handling and labeling of laboratory specimens. The procedure guidelines define the process steps for obtaining a specimen and notification of pick-up of the specimen. (DI #3, p. 47, att. 18). In addition, the applicant's policy states a laboratory request slip identifying the patient, physician, diagnosis, and laboratory or pathology work is sent to the laboratory or accompanies the patient to the laboratory service. The policy also states routine pathology sent out by the ASC will be logged as to patient name, specimen number, description of specimen, date, laboratory, and date report returned. (DI #3, p. 47, att. 18).

Diagnostic radiology services are provided using a C-Arm, a low-level radiation machine, which is available within the operating suites. As part of the annual competency, qualified and trained staff can perform fluoroscopy[14] and C-Arm services. A physician operates the C-Arm controlling the emission of radiation or a certified X-Ray technician will be available. (DI #3, p. 47, att. 19).

Staff Analysis

[14] A medical procedure that makes a real-time video of the movements inside a part of the body

Staff reviewed the submitted policies and agreements in place regarding laboratory, radiology, and pathology services provided by the applicant. Harborside has policies in place to provide support services for its patients. Its staff is trained annually on the proper procedures to follow for laboratory and pathology collection. Qualified staff are trained to provide imaging services using a C-Arm in the operating rooms.

Staff concludes that applicant complies with this standard.

(6) Patient Safety. The design of proposed surgical facilities or changes to existing surgical facilities shall include features that enhance and improve patient safety. An applicant shall:

(a) Document the manner in which the planning of the project took patient safety into account; and
(b) Provide an analysis of patient safety features included in the design of proposed new, replacement, or renovated surgical facilities.

Applicant Response

In the changes to the existing surgical facility Harborside states that patient safety will not be compromised and that it conducted an initial risk assessment to define potential risks for patients, including issues that might be created by the renovation during construction It also stated it will adhere to FGI guidelines for safety. The move of the double doors to expand the sterile corridor to include the new OR, converted from a procedure room outside the sterile corridor, will ensure sterility will be maintained in the new OR.

Further, applicant outlines the following plans and design elements that will be in place for the renovations:

(1) Work will be completed on Saturday and Sunday between the hours 6-2:30 to not disrupt the patient flow and decrease risk of infection by not having work occurring while patients are present within the surgery center;
(2) Sunday evening when work is complete, all trash and debris will be removed from the worksite, and a terminal clean will be performed to ensure operating suite is clean and ready for services on Monday morning;
(3) A terminal clean check list will be completed by the cleaning staff;
(4) Prior to operations resuming on Monday morning, the facility administrator or designee will before a walk through with staff to ensure areas are clean, free of dust and all airflow and systems are working appropriately;
(5) The designated area of work will be contained by zip walls; and
(6) One month prior to start of construction, an infection control meeting will be held.

The applicant states that it followed all accreditation and Maryland safety standards and guidelines available. (DI #3. p. 48).

Staff Analysis

Harborside considered patient safety in the design of this limited project. The construction will occur on weekends when no patients will be at the facility. The applicant provided a letter from the project architect stating that patient safety will be addressed by compliance with the FGI guidelines, with proper finish selections to maximize the ability to sanitize the space. (DI #9, att. 35). Staff concludes that the applicant considered patient safety in its design of the proposed ASF and developed a plan to ensure construction did not compromise patient safety.

Staff concludes that applicant complies with this standard.

(7) Construction Costs. The cost of constructing surgical facilities shall be reasonable and consistent with current industry cost experience.

(a) Hospital projects.

(i) The projected cost per square foot of a hospital construction or renovation project that includes surgical facilities shall be compared to the benchmark cost of good quality Class A hospital construction given in the Marshall Valuation Service® guide, updated using Marshall Valuation Service® update multipliers, and adjusted as shown in the Marshall Valuation Service® guide as necessary for site terrain, number of building levels, geographic locality, and other listed factors.

(ii) If the projected cost per square foot exceeds the Marshall Valuation Service® benchmark cost, any adjustment of the hospital's global budget revenue authorized for the hospital related to the capital cost of the project shall not include:

1. The amount of the projected construction cost and associated capitalized construction cost that exceeds the Marshall Valuation Service® benchmark; and

2. Those portions of the contingency allowance, inflation allowance, and capitalized construction interest expenditure that are based on the excess construction cost.

(b) Ambulatory Surgical Facilities.

(i) The projected cost per square foot of new construction shall be compared to the benchmark cost of good quality Class A construction given in the Marshall Valuation Service® guide, updated using Marshall Valuation Service® update multipliers, and adjusted as shown in the Marshall Valuation Service® guide as necessary for site terrain, number of building levels, geographic locality, and other listed factors. This standard does not apply to the costs of renovation or the fitting out of shell space.

(ii) If the projected cost per square foot of new construction exceeds the Marshall Valuation Service® benchmark cost by 25% or more, then the applicant's project shall not be approved unless the applicant demonstrates the reasonableness of the construction costs. Additional independent construction cost estimates or information on the actual cost of recently constructed surgical facilities similar to the proposed facility

may be provided to support an applicant's analysis of the reasonableness of the construction costs.

This standard is not applicable, Harborside does not propose to undertake any new construction in connection with this renovation project.

(8) Financial Feasibility. A surgical facility project shall be financially feasible. Financial projections filed as part of an application that includes the establishment or expansion of surgical facilities and services shall be accompanied by a statement containing each assumption used to develop the projections.

(a) An applicant shall document that:

(i) Utilization projections are consistent with observed historic trends in use of each applicable service by the likely service area population of the facility;

(ii) Revenue estimates are consistent with utilization projections and are based on current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity care provision, as experienced by the applicant facility or, if a new facility, the recent experience of similar facilities;

(iii) Staffing and overall expense projections are consistent with utilization projections and are based on current expenditure levels and reasonably anticipated future staffing levels as experienced by the applicant facility, or, if a new facility, the recent experience of similar facilities; and

(iv) The hospital or ambulatory surgical facility will generate excess revenues over total expenses for the specific services affected by the project (including debt service expenses and plant and equipment depreciation), if utilization forecasts are achieved for the specific services affected by the project within five years of initiating operations.

(b) A project that does not generate excess revenues over total expenses even if utilization forecasts are achieved for the services affected by the project may be approved upon demonstration that overall facility financial performance will be positive and that the services will benefit the facility's primary service area population.

Applicant Response

For paragraph (a) the applicant demonstrated in the need standard (*supra, pp. 16-22*) that the utilization projections (*supra, Table III-2, p. 16*) are consistent with observed historic trends for the surgeons currently practicing at Harborside, the total procedures, and the service area population.

The applicant based its revenue estimates on the utilization projections and current charges and rates of reimbursement. (DI #9, p. 32 and DI #2, Exhibit 4, Table G). The applicant states that the projected revenue estimates align with the increases in projected volume. Each individual physician's projected case volume for CY 2023-2026 was provided and based on the individual physician's historical trends, their current and projected weekly working schedules, and a

projected growth in their procedure volume. Physician volume growth over the projected period align with the currently employed physician volumes. (DI #3, p. 51-54, DI #9, pp. 19-22).

For subpart (iii) the applicant based its projected staffing levels on current utilization projections and OR staffing experience. (DI #11, p. 32). Harborside expects to hire eight direct care full-time employees (FTEs), six registered nurses and two surgical technologists, to accommodate the increase in volume that will result from this project. (DI #11, Table L).

Harborside's currently and continuing to FY 2026 actual and projected revenues and expenses are shown in Table III-5.

Table III-5: Harborside Revenues and Expenses, Recent Years CY2022-CY2023 and Projected Years CY2024-CY2028

	Two Most Recent Years (Actual)		Projected Years				
	CY2022	**CY2023**	**CY2024**	**CY2025**	**CY2026**	**CY2027**	**CY2028**
OR Cases	1,151	1,846	2,145	2,376	2,676	2,959	3,032
Net Operating Revenue	13,410,235	21,635,284	27,645,139	30,609,231	34,535,540	38,221,243	39,265,367
Total Operating Expenses	13,251,974	20,860,076	24,802,953	27,144,305	29,754,451	30,023,386	32,818,068
Net Income/ (Loss)	158,260	775,208	2,842,186	3,464,926	4,781,089	6,197,857	6,447,299

Source: (DI #9, Table 8, p. 16, att.34.)

Paragraph (b) is not applicable.

Staff Analysis

Staff reviewed the Need Standard (*supra, pp. 16-20*) and concludes that Harborside demonstrated that the utilization projections are within the observed historic limits in terms of growth in service area population.

For paragraph (a)(ii), Harborside has provided utilization projections along with revenues and expenses in Tables 1 and 3 respectively, using CY 2023 as the base year. Per Appendix 7, Net Patient Services Revenue which includes Gross patient service revenue, allowance for bad debt, charity care, and contractual allowances is observed to grow at a CAGR of 13.5 percent, $21,475,883 (CY 2023) to $40,402,675 (CY 2028) during the five-year period. Direct patient care expenses which includes Salaries, Wages, and Professional Fees, fringe benefits), contractual services, supplies and other expenses are projected to grow at a slightly higher CAGR of 13.7 percent, $14,549,270 (CY 2023) to $27,645,934 (CY 2028) during the same 5-year period. Growth in revenues and expenses closely follows the rate of growth of the facility volume.

While Harborside did not explicitly provide any information related to rates of reimbursements or fee schedules, the Statement of Financial Assumptions (per DI #3, p 240,

Attachment 20) states that the charge per case is based on charges and utilization from CY 2023. Staff derived gross patient revenue per case and observed a CAGR of 2.6 percent, $44,573 (CY 2023) to $50,794 (CY 2028) (Appendix 6 and Appendix 7). This aligns with the increase in cost per case with a similar CAGR of 2.7 percent, $4,777 (CY 2023) to $5,461 (CY 2028) (Appendix 6 and Appendix 8). Escalations in cost of care are anticipated over time as the organization grows. However, upon inspection of the cost to charge ratio it appeared stable at 0.11 throughout the five-year period (Appendix 8). This strengthens staff opinion that the revenue estimates are consistent with utilization projections at the facility-level.

For paragraph (a)(iii), Harborside plans on hiring eight full-time staff for the proposed OR. Harborside plans to phase in the additional staff by the end of the projection period which is CY 2028 which would be the third full year of optimal capacity utilization post implementation. The total cost of the extra staffing would be $764,234 (DI #3, pp. 241-248, Table L, p 245). The addition of these eight FTEs is reasonable considering the applicant's projected increase in volume.

The applicant projected positive financial results, as shown in Table III-4. Its assumed utilization projections are reasonable based on the historical volumes and the projected increased demand for surgical procedures due to an aging population. The revenue and expense projections, as well as projected staffing levels are based on current experience, utilization projections and current charges.

To reconcile Table L (DI #3, p 245) with Table 3 (DI #3, p 65) Harborside shared the breakout of the salaries and wages versus benefit expense (DI #11, p 8) and the two tables tie together. At the facility level the salaries (without benefits) are expected to grow at a CAGR of 9.3 percent ($3,008,612 in CY 2023 to $4,696,424 in CY 2028) in tandem with growth in overall operating expenses and total facility volume. The FTE cost of $4.6M in CY 2028 includes the phased in staffing cost of $764,234. Overall FTE salaries (with benefits) are also expected to grow at a similar CAGR of 9.5 percent ($3,942,055 in CY 2023 to $6,198,313 in CY 2028) and tallies with Table 3 (per DI #3, p 65).

For paragraph (a)(iv), staff found that operating income at the facility level was expected to grow at a CAGR 57.2 percent from $775,208 (CY 2023) to $7,430,997 (CY 2028). Similarly, operating profit margin is expected to grow from 3.6 percent (CY 2023) to 18.3 percent (CY 2028). These two increases are a key indicator of profitability (Appendix 9).

Per the CON application (DI #3, p 63) Harborside will arrange for the cost of the project ($250,000, DI #3, p14) from its internal financial reserves. The applicant has a considerable amount of annual amortization expense ($4.3M) and depreciation expense (over $750K) incurred historically as well as for the years projected. In absence of source of this debt, including principal amount, term and interest rates elaborate amortization schedules could not be built and hence debt service could not be computed. However, staff inspected the growth in Earnings Before Interest Tax Depreciation and Amortization (EBITDA) which is the ability to generate cash from core patient services (Appendix 9). Harborside generated EBITDA of $7,086,014 in CY 2023 and is expected to generate $13,056,623 by CY 2028 with a 5-year CAGR of 13 percent. Thus, staff concludes that the level of cash flow and the periodic portion of the liabilities at Harborside appears reasonable from a standpoint of a growing facility.

Staff also reviewed the letter from certified public accountant that confirms the financial position of Harborside stating the applicant "would have sufficient liquidity to convert their existing procedure room to an operating room." (DI #3, p. 243-244 Attachment 21).

Overall, Harborside demonstrates sustained profitability and sufficient liquidity with the assurance that the proposed project is not going to be serviced using external debt. These factors lead the staff to conclude the financial feasibility of Harborside to generate excess revenue over expenses within five years of project initiation and hence can be considered compliant with this standard.

Paragraph (b) is not applicable, as Harborside does generate excess revenue over total expense.

Staff concludes that applicant complies with this standard.

(9) Impact.

(a) 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):

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

(ii) A minimum of two years of historic surgical case volume data for each physician or other 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 other practitioners; and

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

(b) An application shall assess the impact of the proposed project on surgical case volume at hospitals:

(i) If the applicant's 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 or more of the operating room time in use at that hospital, the applicant shall include, as part of its 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.

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

Applicant Response

Harborside provided historic (2023) and projected surgical volume for 2023 to 2028. (DI #3, p. 52). The applicant states that it only became an ASC-2 in 2023, thus only the year 2023 is provided. The applicant provided the current number of cases performed by Harborside physicians at hospital outpatient surgery departments and ambulatory surgery centers. The applicant states that it does not have access to operating room time per cases at these facilities. All the non-Harborside facilities at which the physicians practice is located in Virginia, except for the Capital Orthopedic Center in Bethesda, Maryland, where only two physicians practice. As stated in the need section, *(supra, pp. 16-20*), the locations in Virginia include two hospitals and one surgery center.

- Inova Alexandria Hospital Outpatient Surgery (hospital)
- Inova Mount Vernon Outpatient Surgery (hospital)
- Inova Healthplex Franconia Springfield (ambulatory surgery center)

The applicant states that no Maryland facilities will be impacted by this project. Based on overall population growth, Harborside expects other facilities to experience growth in volumes given the aging population and the growth in complex surgical procedures migrating from the inpatient to the outpatient setting. Harborside states that the impact on existing facilities from the shift of cases to Harborside will be mitigated by future growth in the total market. (DI #3, p. 57).

The applicant stated that no Maryland hospitals will be impacted. (DI #3, p. 58). The applicant relied on the signed statements of its surgeons to determine any shifts in volumes. (DI #3, p. 54). It summarized this data in Table 14 of the response (DI #3, pp. 55-6, DI #9, p. 20). The applicant also had provided information from the surgeons on what volume was projected to remain at existing facilities (DI #3, p. 57, Table 15). To demonstrate impact on the existing hospital providers in Virginia, the applicant provided an analysis in Table III-6 based on the surgeons' responses. (DI #9, p.21).

Table III-6: Harborside Potential Impact on Viriginia Hospitals: Shift in Physician Volume

	CY2025	**CY2026**	**CY2027**
Cases Shifted to Harborside	561	906	1,241
Percent of Surgical Cases	61.2%	62.6%	63.7%
Surgical Cases	343	567	791
Pro-rated Totals Below			
Inova Mount Vernon (57.0%)	196	323	451
Inova Alexandria (20.5%)	70	116	162
Virginia Surgical Cases in CY2022 (Applied to 2025-2027)			
Inova Mount Vernon	4,513	4,513	4,513
Inova Alexandria	7,118	7,118	7,118
Harborside Impact on			
Inova Mount Vernon	**4.3%**	**7.2%**	**10.0%**
Inova Alexandria	**1.0%**	**1.6%**	**2.3%**

Source: DI #9, p. 21, the 2022 discharge data is from Viriginia Health Information (www.vhi.org)

Based on this analysis, the applicant determined the impact on the volume on the two Viriginia hospitals was at most 10 percent. (DI #9, pp. 21-22). The applicant states that there will

be no impact to Maryland hospitals and minimal impact to Maryland ASCs/ASFs as the increase in cases will be accounted for by the shift of patients primarily from facilities outside of Maryland. (DI #3, p. 44).

Staff Analysis

Staff reviewed the historical and projected data submitted by the applicant. Surgery case volumes were based on physician responses. (DI #3, pp. 55-6, table 14). The applicant states that much of the new case volume will come from an aging population which has a higher utilization rate. The applicant previously provided demographic analysis regarding the service area in the need standard, which indicated that the age 65+ population cohort was projected to grow at a rate greater than the total population. This will also drive increased volumes for all providers in the service area. *(supra, pp. 15-16).*

Staff reviewed the information submitted on the impact on existing hospitals. The applicant derives most patients from northern Virginia, and hospitals in that region are where all surgeons with admitting privileges exist. (DI #3, p. 44). The applicant provided an analysis where projected impact on existing providers is below the threshold of 18 percent as required in the standard. This is based on estimates, so it is only a best approximation. While some volume will be shifted from the existing hospitals in Virginia, it is not so substantial to negatively impact the financial viability of the hospitals.

Staff concludes that the applicant complies with this standard.

B. COMAR 10.24.01.08G (3)(b)-Need.

The Commission shall consider the applicable need analysis in the State Health Plan. If no State Health Plan need analysis is applicable, the Commission shall consider whether the applicant has demonstrated unmet needs of the population to be served and established that the proposed project meets those needs.

This criterion directs the Commission to consider the "applicable need analysis in the State Health Plan." The discussion for this recommendation can be found in the Surgical Services Chapter at COMAR 10.24.11.05B(2), Need – Minimum Utilization for Establishment of a New Facility.

In staff's review of the applicable State Health Plan need standard (Project Review Standard 2- Need- Minimum Utilization for Establishment of a New or Replacement Facility (*supra, pp. 16-20,)* staff concludes that applicant's projected utilization growth is reasonable, and that Harborside is likely to meet the minimal capacity use standard for a three OR ASF.

Staff recommends that the Commission find that the applicant demonstrated a need for the proposed project.

C. COMAR 10.24.01.08G(3)(c)-Availability of More Cost-Effective Alternatives

The Commission shall compare the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities, or alternative facilities which have submitted a competitive application as part of a comparative review.

Applicant Response

Harborside states that after its relocation and change from an ASC-1 to ASC-2 in February 2023, the two ORs experienced significant growth in utilization for the remainder of that year. It undertook a planning process with a goal of identifying the best alternative to accommodate the need of the surgeons on its staff to offer timely surgery in a freestanding environment for its patients. (DI #3, p.p. 61-2). As discussed in the need section *(supra, pp16-20),* the two existing ORs cannot accommodate the current demand.

The applicant's planning process identified three alternatives:

(a) Maintain the status quo in terms of available capacity
(b) Add new ORs
(c) Convert one existing procedure room to an OR.

The applicant stated that maintaining the status quo would be unacceptable because it ignores the capacity constraints that Harborside is currently experiencing with the demand that exists in the market. Without OR expansion, some patients of Harborside surgeons would receive surgical care in a hospital setting, which results in higher costs, greater safety risks, and less convenient care, or they would experience scheduling delays. (DI #3, pp. 61-2).

Harborside states it also considered maintaining its existing complement of rooms and adding one or two additional ORs. The applicant did not obtain cost estimates for an OR construction project, but it presumed this alternative would be more costly given that it would require expansion of the existing sterile space. Also, expanding the space would be disruptive to current operations. For these reasons, this alternative was rejected. (DI #3, p. 62).

The applicant states the chosen alternative, to convert one existing procedure room that would undergo minimal renovations for conversion to an OR, best met the goal of expanding Harborside's capacity without the more significant cost and disruption that an expansion would entail. Harborside states it can accommodate current and projected procedural volumes in the two remaining procedure rooms. Moreover, there is minimal cost and disruption associated with converting the procedure room to an OR. This procedure room was built to OR standards when the facility was constructed, just for this scenario. As this was the case, Harborside did not conduct a detailed architectural review of the option of adding a third operating room (DI #9, p. 4, p. 23). The floor plan that shows the location of the procedure room next to the existing ORs is included in Appendix 3 of the report.

Staff Analysis

The applicant has provided an explanation that supports that this project is the most cost-effective alternative to alleviating the growth in volume and resulting scheduling strain. The

procedure room that is the proposed space was originally designed to OR specifications and shares the existing air handling capabilities of the other ORs. (DI #9, p.4). Relocation of the double doors down a hallway to expand the sterile corridor to include the new OR is a cost-effective option. The expansion of an existing facility from two to three ORs should result in space that is more economical to operate.

Staff recommends that the Commission find that the project is cost effective.

D. Project Financial Feasibility and Facility or Program Viability

COMAR 10.24.01.08G(3)(d) The Commission shall consider the availability of resources necessary to implement the project and the availability of revenue sources and demand for the proposed services adequate to ensure ongoing viability and sustainability of the facility to be established or modified or the service to be introduced or expanded.

Applicant Response

Availability of Resources to Implement the Proposed Project

The applicant states that the project, with an estimated cost of $247,985 will be funded with cash. The availability of these funds is documented in the letter provided by Michael E. Wicks, CPA, of Kositzka, Wicks and Company, who states that this firm reviewed the financial statements for Harborside for FY 2023 and for four months ending April 2024. (DI #3, p. 62, att. 21).

Availability of Resources to Sustain the Proposed Project

Harborside expects to hire eight new direct care FTEs (six registered nurses and two surgical technologist) to accommodate the increase in volume that will result from this project. The total cost for the eight FTEs is $764,234. (DI #11, Table L).

Projected operating results for the surgical center were shown earlier, in the Financial Feasibility standard in Table III-5 *(supra, pp. 25-28).* Harborside has demonstrated that the expanded facility is likely to generate excess revenue over expenses. Accounting for new FTEs, the applicant still projects positive total revenues for the facility more than $4.7 million in the first year of operation (CY 2024), ramping up to over $6.4 million by CY 2028. (DI #9, Table G).

Staff Analysis

The applicant provided a reasonable cost estimate and staffing plan for the project, The project was shown to be financially feasible in a previous standard. (*supra, pp. 25-28).*

Staff recommends that the Commission find that the proposed project is viable.

E. Compliance with Conditions of Previous Certificates of Need

COMAR 10.24.01.08G(3)(e) An applicant shall demonstrate compliance with all terms and conditions of each previous Certificate of Need granted to the applicant, and with all commitments made that earned preferences in obtaining each previous Certificate of Need or provide the Commission with a written notice and explanation as to why the conditions or commitments were not met.

Applicant Response

Harborside states it has not received prior CON approvals from the Commission. The Commission did issue to Harborside a Determination of Coverage dated January 25, 2021 for a change of ownership for an existing ASC with one sterile operating room and two non-sterile procedure rooms located at 125 Potomac Passage, Suite 200 in Oxon Hill, Maryland 20745. In a subsequent determination request letter from the Commission dated February 17, 2023, the Commission issued a determination for Harborside Surgery Center to replace and relocate the ASC to its new location at 251 National Harbor Boulevard, Suite 200 in Oxon Hill, Maryland 20745. The February 2023 letter also acknowledges that Harborside would change its scope to become an ASC-2 with the addition of a second sterile OR and a third non-sterile procedure room without CON review. (DI #3, p. 70).

Staff Analysis

The applicant has not previously applied for a CON. It discussed previous Commission issued Determinations of Coverage for the ASC, for which it has been compliant.

The criterion does not apply as the applicant has not received a prior CON.

F. Impact

COMAR 10.24.01.08G(3)(f) Impact on Existing Providers and the Health Care Delivery System. An applicant shall provide information and analysis with respect to the impact of the proposed project on existing health care providers in the health planning region, including the impact on geographic and demographic access to services, on occupancy, on costs and charges of other providers, and on costs to the health care delivery system.

Impact on other providers and facilities

Applicant Response

As described in the Impact standard earlier in this report, *(supra, pp. 28-30),* the new case volume, which increases from a projected 6,991 procedures in 2025 to 8,884 in 2028, will largely come from an aging population (65+) in the service area. (Appendix 6). Because orthopedic procedures, the main surgical service at Harborside, present cases which are low risk and one of the most common elective surgery procedures provided in an ambulatory surgery setting, the types of procedures being performed at Harborside will not shift many cases out of the hospital setting. Harborside physicians have credentials at Inova Mt. Vernon and Viriginia Hospital Center. A majority are employed by either Anderson Orthopaedics, Washington Ortho Sports Medicine,

OrthoVA or Nirshl Orthopedic Center in Virginia. (DI #9, pp. 35-36). Lastly, Harborside submitted data that identifies the physicians and the historic number of surgical cases (CY 2022 and CY 2023) as well as the projected number of cases at the proposed ASF, and what the shift will be from other facilities. (DI #3, Table 14, p. 55).

Impact on access to health care services, system costs, and costs and charges of other providers

Harborside states that the proposed project will have an overall positive impact on the local healthcare delivery system because it is increasing access for an aging population to receive routine necessary surgical procedures. The applicant supplied articles from Leapfrog Group, Becker's ASC publication, Health and Human Services, and other journals to support the quality and cost savings ASCs provide to patients, payors, and the community (DI #9, pp. 2-4, att. 27-32, DI #11, p.6).

Staff Analysis

Staff concludes that the project is not likely to have an undue negative impact on existing providers, as the population aged 65 and over is growing in the service area. This population will be a major driver of increased demand for the surgical procedures at the facility. Staff reviewed the articles submitted by the applicant to verify the information provided. Based on the information presented in various journals, an ASF will have lower costs and better outcomes for the patients selected to have surgery in an ambulatory setting. The care and services Harborside plans to provide will positively affect costs to the health care delivery system.

Staff recommends that the Commission find that the project will have an impact that is positive.

G. Health Equity

COMAR 10.24.01.08G(3)(g) Health Equity. The Commission shall consider how a proposed project will address health care disparities in availability, accessibility, and quality of care among different populations within the service area. The Commission shall consider how social determinants of health within the service area of the proposed project create disparities in the delivery of health care.

Applicant Response

The applicant stated that its service area is racially and ethnically diverse and provided information from the US Census. (DI #3, p. 72). The information provided is included in Table III-7 below.

Table III-7: Harborside Service Area Jurisdictions Population Estimate by Race

Fact	Fact Note	Fairfax County, VA	Arlington County, VA	Alexandria City, VA	Prince William County, VA	Prince George's County, MD	United States
Population estimates, July 1, 2023, (V2023)		1,141,878	234,162	155,230	489,640	947,430	334,914,895
Persons aged 65 and over		15.60%	12.40%	12.30%	11.80%	15.60%	17.70%
White alone		63.20%	73.20%	56.70%	60.70%	28.10%	75.30%
White alone, not Hispanic		47.70%	59.40%	51.10%	38.20%	11.00%	58.40%
Black or African American alone	(a)	11.10%	10.70%	21.30%	21.90%	62.90%	13.70%
American Indian and Alaska Native alone	(a)	0.60%	0.70%	0.30%	1.10%	1.60%	1.30%
Asian alone	(a)	20.80%	11.30%	6.40%	11.10%	4.30%	6.40%
Native Hawaiian and Other Pacific Islander alone	(a)	0.10%	0.20%	0.00%	0.20%	0.20%	0.30%
Two or More Races,		4.20%	4.00%	10.00%	5.10%	2.90%	3.10%
Subtotal		84.50%	86.30%	89.10%	77.60%	82.90%	83.20%
Hispanic or Latino,	(b)	17.70%	16.00%	16.60%	26.30%	22.80%	19.50%
Total Estimate	**(c)**	**102.2%**	**102.3%**	**105.7%**	**103.9%**	**105.7%**	**102.7%**
Fact Notes							
(a)	Includes persons reporting only one race						
(b)	Hispanics may be of any race, so also are included in applicable race categories						
(c)	Total may be above 100% as Hispanic may be included in multiple race categories						

Source: https://www.census.gov/quickfacts/fact/table/ with the following selected: Fairfax County Virginia, Arlington County Virginia, Alexandria City Virginia, Prince William County Virginia, Prince George's County Maryland.

Applicant has also stated its staff is racially and ethnically diverse, giving patients access to diverse care providers in a high-quality ambulatory surgery setting. As discussed in the Quality Rating standard (*supra, pp. 11-14)*, Harborside has demonstrated that in addition to having a diverse workforce, it also provides quality care in its ambulatory surgery center. The race and ethnicity of the providers and staff is shown in Table III-8.

Table III-8: Harborside Staff Demographics

Race or Ethnicity	Medical Staff	Other Employees
White	58%	54%
Black	17%	24%
Hispanic	0%	10%
Asian	25%	8%
All Other	0%	4%

Source: DI #3, p. 72.

The applicant states that as outlined in the Harborside Surgery Center Employee Manual, its hiring practices adhere strictly to the principle of equal employment opportunities, and states that it is dedicated to providing fair and equitable treatment to all individuals, irrespective of race, color, creed, sex, marital status, age, national origin, physical handicap, disability, medical condition, or ancestry. (DI #3, p. 73).

Harborside Surgery Center states it recognizes the critical importance of providing ongoing competency training for its staff and medical professionals to ensure that its healthcare professionals possess the necessary competence to understand key concepts such as social determinants of health (SDOH), implicit bias, and cultural competence. Harborside states that as part of its commitment to creating a workplace environment that values cultural competence and inclusivity, it requires all staff to complete courses on these three concepts during onboarding and on an annual basis thereafter.

To demonstrate its commitment to health equity, Harborside has supported Operation Walk Virginia. Medical staff members who participate in the walk also give donations of medications, and supplies on mission trips providing hip and knee surgeries to patient in Central and South America. To increase Harborside's commitment to increasing access to care within the community it is also exploring a partnership with Operation Walk USA (http://operationwalkusa.org/). Established in 2011, Operation Walk USA is a medical charitable organization, dedicated to assisting uninsured patients in the United States who require hip or knee replacement surgeries. The applicant notes that historically, Operation Walk USA has collaborated with hospital partners. Harborside is interested in exploring the possibility of extending this partnership to the ambulatory surgery setting. (DI #3, p. 77, DI #9, p. 26).

Harborside states that in the development phase of the facility, it has not conducted outreach programs in the community, but states that in good faith, it intends to develop an outreach clinic to perform annual musculoskeletal screening for arthritis and fall risk in the community and to coordinate with Prince George's Department of Health and other health clinics in the area to promote the screenings. (DI #9, p. 27) Harborside states that prior to first use, it will adopt a policy stating that annually, as part of the budgeting process, it will include a discussion with its Board to identify necessary resources needed to address its commitment to outreach that promotes health equity. (DI #9, p. 27).

Staff Analysis

The criterion asks for how this project will address health care disparities. The term "health disparities" is defined as a difference in which disadvantaged social groups—such as people with lower socioeconomic status, racial and ethnic minorities, women and other groups who have persistently experienced social disadvantage or discrimination—systematically experience worse health or greater health risks than more advantaged social groups.[15] Health disparities are caused by a multitude of factors referred to as social determinants of health (such as but not limited to

[15] https://www.nimhd.nih.gov/resources/understanding-health-disparities/minority-health-and-health-disparities- definitions.html

safe housing, healthy food, access to health services, transportation, public safety, media and technology).[16]

In review of the criterion, staff notes that the applicant requires all staff to complete courses on three key concepts in health equity that address SDOH, Implicit Bias, and Cultural Competence training during onboarding and on an annual basis thereafter. The training is designed to enhance an employee or healthcare provider's ability to deliver effective, equitable care and demonstrates applicant's commitment and contributions to improve health care disparities in the service area. In addition, Harborside has plans to develop a partnership with Operation Walk USA to provide recuperative orthopedic surgery in an ambulatory setting. This would be an alternative to Operation Walk USA's existing partnerships that are all hospitals. In review of the organization's website, staff found that Operation Walk USA worked with 20 hospital organizations across the United States, including two in Virigina, and one in both West Virginia and Maryland. (http://operationwalkusa.org/physiciansignup/). Harborside also states it will work with the Prince George's County Health Department to develop and assist in providing public health screening services for arthritis care and to promote fall reduction strategies.

Staff recommends that the Commission find that the applicant complies with this criterion, with the following condition:

> Harborside will adopt a policy stating that annually, as part of the budgeting process, Harborside will include a discussion with its Board to discuss and identify necessary resources needed to address its commitment to Health Equity. Before first use, Harborside will identify the specific social determinants of health of their service area and submit a plan as to how this project plans to address it, including updated plans for the outreach clinic, and their discussions with Prince George's county department of health.

H. Character and Competence

COMAR 0.24.01.08G(3)(h) Character and Competence. The Commission shall assess the character and competence of an applicant based upon experience and past performance, including any records of violation in operating a health care service or facility.

Applicant Response

To demonstrate compliance with this criterion the applicant provided the names and addresses of all owners and individuals identifying their ownership share percentage in the facility. The complete list of owners is included as Appendix 4. The applicant also provided the following list of individuals who have any involvement in the ownership, development, or management of another health care facility.

[16] https://www.thenationalcouncil.org/resources/integrated-health-coe-toolkit-purpose-of-this-toolkit/module-3- health-disparities-social-determinants/

Table III-9: Ownership with Involvement in Another Health Care Facility

Physician	Facility	City/State
George Branche III, M.D.	Fairfax Surgical Center	Fairfax, Virginia
Michael Nathan, M.D.	Fairfax Surgical Center	Fairfax, Virginia
Ben Kitteridge, M.D.	Inova Franconia Springfield Surgery Center OrthoVirginia Herndon	Alexandria, Virginia Herndon, Virginia
Andrew Wolff, M.D.	Massachusetts Avenue Surgery Center	Bethesda, Maryland

Source: DI #3, p. 78

The applicant states that none of the individuals or facilities identified in Table III-9 have had its license suspended or revoked or been subject to any disciplinary action (such as a ban on admissions) in the last 5 years. The applicant also states that none of the owners and individuals responsible for the project identified above have ever pled guilty to or been convicted of a criminal offense in any way connected with the ownership, development, or management of the applicant facility or any of the health care facilities. (DI #3, p 79).

Staff Analysis

Staff reviewed the applicant's submission and the applicant's website[17]. The website states the "Center meets the highest industry standards for top-quality health care, is certified by Medicare, licensed by the state, and fully accredited by the Accreditation Association for Ambulatory Health Care (AAAHC)." The licensure and certification are a demonstration of the applicant's character and competence by indicating it meets the required standards of care. In addition, in its analysis to demonstrate character and competence the applicant disclosed four different physicians that have ownership in four other ambulatory surgical facilities both in Maryland and Virginia and that none have ever pled guilty to or been convicted of a criminal offense in any way connected with the ownership, development, or management of these health care facilities. Staff concludes that the information provided is credible and that the applicant has sufficiently documented its character and competence.

Summary

MHCC staff conclude that this project complies with the State Health Plan standards and that the applicant has demonstrated the need for the project, its cost-effectiveness, its viability, its positive impact, and a commitment to health equity and character and competence in facility management. Staff summarizes its findings regarding the criteria below.

Need and Capacity

Staff concludes that the applicant has successfully demonstrated the need for this project.

[17] https://harborsidesurgcenter.com/

This includes the need for a new, third operating room. Staff concluded that the applicant's assessment of need to be reasonable and consistent with current trends in ambulatory surgical facility use and the changing surgical service delivery environment and payment for surgical services.

Cost and Effectiveness

Harborside has adequately demonstrated that the proposed renovation is a cost-effective approach to the surgical services needed and that the new operating room offers improved access to service area residents.

Financial Feasibility and Viability

The staffing, and revenue/expense projections demonstrate that the project can be both financially feasible and viable. Staff reviewed applicant's financial plans and projections and anticipates that the ASF, once completed, will likely be profitable, assuming the applicant maximizes increased efficiencies.

Impact

The proposed project will have a positive impact on existing health care providers in the service area, including geographic and demographic access to services, occupancy, costs and charges of other providers, and costs to the health care delivery system. Staff concludes that there will not be a negative impact on other providers or the health care delivery system due to the implementation of this project.

Health Equity

The applicant requires all staff to complete courses on three key concepts in health equity to help employees remember to be culturally sensitive when providing care. Harborside plans to coordinate with Prince George's Department of Health and other health clinics in its service area to promote health screenings as one way to overcome existing health care disparities in the community. Harborside is developing a commitment to health equity.

Character and Competence

Harborside provided information on its ownership. There have been no known violations of practitioners or facilities, and it holds accreditation from the Association for Ambulatory Health Care (AAAHC). Its most recent AAAHC survey resulted in full compliance.

IV. SUMMARY AND STAFF RECOMMENDATION

Based on the review of applicant's compliance with the Certificate of Need review criteria (COMAR 10.24.01.08G(3)(a) through h) and with the applicable standards in the General Surgical Services Chapter of the State Health Plan (COMAR 10.24.11), Commission staff recommends that the Commission issue a Certificate of Need to Harborside Surgery Center for a Certificate of Need

to convert an existing procedure room into a third sterile operating room. Staff concludes that the applicant demonstrated that the project complies with the applicable standards in the Surgical Services Chapter, and all applicable criteria, as summarized above.

Accordingly, Staff recommends that the Commission APPROVE Harborside Surgery Center's application for a Certificate of Need authorizing the addition of one operating room to its existing facility located at 251 National Harbor Boulevard, Suite 200 in Oxon Hill, Prince George's County, thereby creating an Ambulatory Surgical Facility, with the following conditions:

> Prior to first use, Harborside shall provide to the public or patient, upon inquiry or as required by applicable regulations or law, information concerning charges for the full range of surgical services provided.
>
> Prior to first use approval, Harborside shall ensure that it provides to the public, upon inquiry or as required by applicable law, the names of the health care carrier networks in which it and its surgeons currently participate.
>
> Prior to first use approval, Harborside shall provide its plan to ensure that it provides charity care that is equivalent to or greater than the average amount of charity care provided by ASFs in the most recent year reported, measured as a percentage of total operating expenses, and that it reports charity care and bad debt, as defined in the FASF[18].
>
> Prior to first use approval, Harborside shall amend its brochure and website to include a link to the medical financial assistance and charity care policies.
>
> Harborside will adopt a policy stating that annually, as part of the budgeting process, Harborside will include a discussion with its Board to discuss and identify necessary resources needed to address its commitment to Health Equity. Before first use, Harborside will identify the specific social determinants of health of their service area and submit a plan as to how this project plans to address it, including updated plans for the outreach clinic, and their discussions with Prince George's county department of health.

[18] COMAR 10.24.11.03 defines "freestanding ambulatory surgical facility," also defined in COMAR 10.05.05.01, is a general licensure category in Maryland Department of Health regulations that includes both an ambulatory surgical facility, a CON-regulated, statutorily-defined health care facility that contains three or more operating rooms, as well as an ambulatory surgical center, which may have only procedure rooms or procedure rooms and up to two operating rooms that is issued a determination of coverage by Commission staff facilities.

IN THE MATTER OF	*	**BEFORE THE**
	*	
	*	
SURGCENTER AT NATIONAL HARBOR, LLC	*	**MARYLAND HEALTH**
	*	
d/b/a HARBORSIDE SURGERY CENTER	*	
	*	
	*	**CARE COMMISSION**
Docket No.: 24-16-2470	*	
	*	

* *

FINAL ORDER

Based on the analysis and conclusions contained in the Staff Report and Recommendation, it, this 21st day of November 2024, by a majority of the Maryland Health Care Commission,

ORDERED:

That the application by Harborside Surgery Center for a Certificate of Need to renovate its existing ambulatory surgery center to have three operating rooms and two procedure rooms at its facility located at 251 National Harbor Boulevard, Suite 200 in Oxon Hill, Prince George's County, at an estimated cost of $247,985 is hereby APPROVED, with the following conditions:

Prior to first use, Harborside shall provide to the public or patient, upon inquiry or as required by applicable regulations or law, information concerning charges for the full range of surgical services provided.

Prior to first use approval, Harborside shall ensure that it provides to the public, upon inquiry or as required by applicable law, the names of the health care carrier networks in which it and its surgeons currently participate.

Prior to first use approval, Harborside shall provide its plan to ensure that it provides charity care that is equivalent to or greater than the average amount of charity care provided by ASFs in the most recent year reported, measured as a percentage of total operating expenses, and that it reports charity care and bad debt, as defined in the Freestanding Ambulatory Surgery Facility Survey.

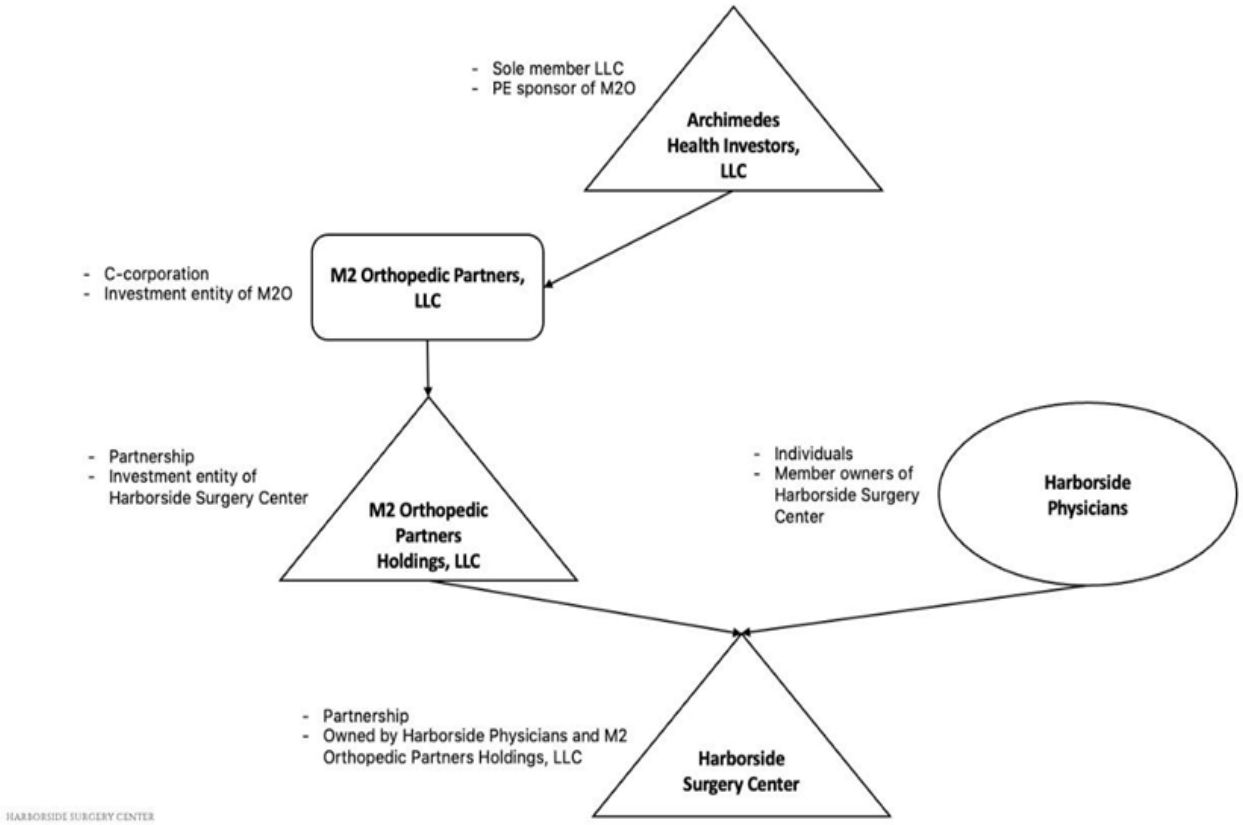
Prior to first use approval, Harborside shall amend its brochure and website to include a link to the financial assistance and charity care policies.

Harborside will adopt a policy stating that annually, as part of the budgeting process, Harborside will include a discussion with its Board to discuss and identify necessary resources needed to address its commitment to Health Equity. Before first use, Harborside will identify the specific social determinants of health of their service area and submit a plan as to how this project plans to address it, including

updated plans for the outreach clinic, and their discussions with Prince George's county department of health.

THE MARYLAND HEALTH CARE COMMISSION

Appendix 1
Ownership Structure



Appendix 2
Record of the Review

Harborside Surgery Center – Docket #24-16-2470

Item #	Description	Date
1	MHCC acknowledges Letter of Intent received from Applicant	4/8/2024
1a	April 2024 email Harborside Charity Care	4/29/2024
2	Pre-Application Conference meeting is held with Applicant	4/17/2024
3	Applicant submits a Certificate of Need application	6/7/2024
4	MHCC acknowledges the receipt of the Certificate of Need Application.	6/7/2024
5	MHCC sends Notice of Receipt of Application Notice to Washington Times	6/7/2024
6	MHCC sends Notice of Receipt of Application Notice to Maryland Register	6/7/2024
7	MHCC sends to applicant a request for Completeness information.	6/28/2024
8	Applicant submits request for extension on Completeness response to MHCC	7/2/2024
9	Applicant's Response to Completeness received	8/1/2024
10	MHCC sends applicant a 2nd Completeness request	8/20/2024
11	Applicant's Response to 2nd Completeness received	9/3/2024
12	MHCC sends notice to Maryland Register- Formal Start of Review	9/4/2024
13	MHCC notifies applicant that the formal start of the review will be 9/03/24	9/4/2024
14	MHCC submits Local Health Officer form	9/4/2024
15	MHCC sends notice to Washington Times that CON application has been docketed	9/4/2024
16	Email correspondence about charity care	10/18/2024
17	Email received regarding departing and new staff physicians	10/31/2024
18	MHCC sends applicant a 3rd Completeness request	11/04/2024
19	Applicant's Response to 3rd Completeness received	11/11/2024

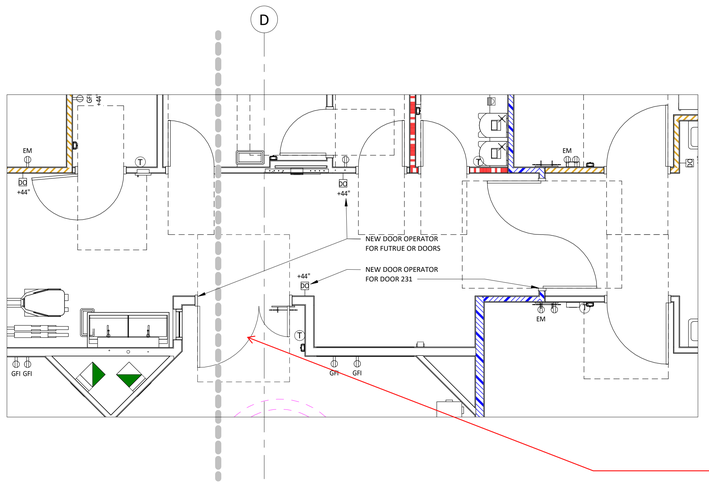
Appendix 3

Floor Plans

APPLICABLE CODES:

PRINCE GEORGE'S COUNTY:
- SUBTITLE 4 BUILDING, MECHANICAL AND ENERGY CODES
- SUBTITLE 9 ELECTRICAL CODE
- SUBTITLE 11 FIRE CODE

COMAR 9.12.53 MARYLAND ACCESSIBILITY CODE
COMAR 10.05 AMBULATORY CARE FACILITIES
2018 INTERNATIONAL BUILDING CODE
2018 INTERNATIONAL ENERGY CONSERVATION CODE
2018 INTERNATIONAL MECHANICAL CODE
2018 INTERNATIONAL EXISTING BUILDING CODE
2018 WSSC PLUMBING AND FUEL GAS CODE
2017 NFPA 70 NATIONAL ELECTRICAL CODE
2018 NFPA 101 CHAPTER 20
MARYLAND STATE FIRE PREVENTION CODE
2022 FGI



NEW DOOR 288. CENTER ON WALL. SEE 6/A2.33 FOR DETAIL. DOOR FRAME IS PREPARED IN EXISTING PARTITION WITH A KNOCKOUT PANEL

2 FLOOR 2 - FUTURE OR CONVERSION (FOR REFERENCE ONLY)
A2.10 1/4" = 1'-0"

1 FLOOR 2 - OVERALL
A5.10 | A2.10 1/8" = 1'-0"

FLOOR PLAN GENERAL NOTES

1. DIMENSIONS ARE TO FACE OF INTERIOR GYPSUM BOARD, TILE BACKER BOARD, FACE OF EXTERIOR WALL MATERIALS, STRUCTURAL GRIDS AND CENTERLINES WHERE INDICATED.
2. ALL GYPSUM WALLBOARD TO BE 5/8" UNO TYPE 'X' EXCEPT AT THE FOLLOWING LOCATIONS:
   A. AT RESTROOMS WITHOUT A SHOWER (TCNA COM2 AREAS), PROVIDE 5/8" UNO MOISTURE AND MOLD RESISTANT GYPSUM BOARD COMPLYING WITH ASTM C1396 FOR WALLS AND BEHIND TILE.
   B. AT WET AREAS INCLUDING BUT NOT LIMITED TO SHOWERS, STERILE PROCESSING ROOMS, JANITOR CLOSETS, SAUNAS, AND SWIMMING POOLS (TCNA COM3/4 AREAS), PROVIDE:
      1. AT TILE AND WALL PROTECTION LOCATIONS: PROVIDE 5/8" UNO COATED GLASS-MAT FACED WATER-RESISTANT GYPSUM WALLBOARD COMPLYING WITH ASTM C1178 OR 5/8" UNO CEMENT BACKER BOARD COMPLYING WITH ASTM C1325
      2. AT PAINTED GYPSUM BOARD LOCATIONS (INCLUDING CEILINGS): PROVIDE 5/8" UNO TYPE 'X' MOISTURE AND MOLD RESISTANT GYPSUM BOARD COMPLYING WITH ASTM C1396
3. PROVIDE RATED ENCLOSURES OR PUTTY PACKS AROUND ALL OUTLETS, BOXES, CABINETS, PIPING, DUCTWORK, ETC., THAT ARE RECESSED IN FIRE-RATED WALLS. ENCLOSE TO PROVIDE SAME RATING AS THE WALL WHERE IT IS LOCATED. SEE SHEET A7.11.
4. DOORS SHALL BE LOCATED 4" FROM ADJACENT PERPENDICULAR WALL TO THE INSIDE EDGE OF THE DOOR FRAME, UNO. SEE DOOR DETAILS ON THE A8 SHEETS.
5. J-BOXES SHOWN BACK-TO-BACK MAY BE ADJUSTED TO OFFSET THE BOXES WITH APPROVAL FROM THE ARCHITECT. SEE SHEET A7.11 FOR DETAILS RELATED TO RECESSED BOXES.

NURSE CALL LEGEND

SYMBOLS

DESIGNATIONS

EP	EMERGENCY PULL
CB	CODE BLUE
CC	PATIENT CALL CORD
AP	ALARM PANEL

DOME LIGHT

- WALL MOUNTED, PLAN VIEW
- WALL MOUNTED, ELEVATION
- CEILING MOUNTED, PLAN VIEW

MEDICAL GAS LEGEND

- O — OXYGEN
- V — VACUUM
- VS — VACUUM SLIDE
- ZONE VALVE BOX
- A — COMPRESSED AIR - WALL
- A — COMPRESSED AIR - CEILING
- AAP-1 — MED GAS AREA ALARM PANEL
- MAP-1 — MED GAS ALARM PANEL

OUT OF SCOPE

NEW PARTITION GRAPHICS LEGEND

GRAPHIC	DESCRIPTION	TYPE	DETAIL	PRIORITY
	1 HOUR SMOKE BARRIER	1Ab	1/A7.10	HIGH
	1 HOUR FIRE BARRIER	1Aa	1/A7.10	↑
	SMOKE PARTITION	0Aa	1/A7.10	
	SOUND PARTITION	0Ac	1/A7.10	
	BRACED PARTITION	0Ba	1/A7.10	
	FURRING PARTITION	0Ab	1/A7.10	↓ LOW

EXISTING PARTITION GRAPHICS LEGEND

GRAPHIC	DESCRIPTION	PRIORITY
	2 HOUR FIRE BARRIER / SHAFTWALL	HIGH
	2 HOUR FIRE BARRIER	↑
	BRACED PARTITION	
	FURRING PARTITION	↓ LOW

1. SEE PARTITION TYPES, SHEET A7.10
2. HIGHEST PRIORITY PARTITIONS ARE LISTED FIRST IN THE LEGEND. SUBSEQUENT PARTITIONS DECREASE IN PRIORITY . HIGHER PRIORITY WALLS TAKES PRECEDENCE, SEE WALL PRIORITY DETAILS.

POWER OUTLET LEGEND

SYMBOLS

- DUPLEX OUTLET
- QUAD OUTLET

DESIGNATIONS

+##"	INDICATES HEIGHT IN INCHES AFF TO OUTLET CENTERLINE. DEFAULT HEIGHT = 18" AFF TO CENTERLINE UNLESS TAGGED OTHERWISE. TYPICAL FOR ALL OUTLETS
D	DEDICATED OUTLET
208v	208 VOLT OUTLET
GFI	OUTLET W/ GROUND FAULT CIRCUIT INTERRUPT PROTECTION
EM	EMERGENCY OUTLET

DATA OUTLET LEGEND

SYMBOLS

- DATA OUTLET
- PHONE OUTLET
- DATA/PHONE OUTLET

DESIGNATIONS

R	RECESSED OUTLET (TYPE PER SYMBOL)

SPECIAL PURPOSE OUTLET LEGEND

SYMBOLS

- SPECIAL PURPOSE OUTLET
- DOMED SECURITY CAM

DESIGNATIONS

TV	TV OUTLET
CR	CARD READER
DO	DOOR OPENER BUTTON
DR	DOOR RELEASE BUTTON
KP	KEYPAD
I	INTERCOM
SC	SECURITY CAMERA

JUNCTION OUTLET LEGEND

SYMBOLS

- JUNCTION BOX OUTLET
- JUNCTION FLOOR OUTLET

DESIGNATIONS

- J^P — JUNCTION BOX OUTLET FOR POWER
- J^W — JUNCTION BOX OUTLET FOR FURNITURE WHIPS
- J^C — JUNCTION BOX OUTLET FOR COMMUNICATION/DATA

MISCELLANEOUS ELECTRICAL LEGEND

- P/D — POWER POLE - 'P' = POWER, 'D' = DATA, 'P/D' = POWER & DATA
- EP — ELECTRICAL PANEL
- GP — GENERATOR ALARM PANEL
- FACP — FIRE ALARM CONTROL PANEL
- FAAP — FIRE ALARM ANNUNCIATOR PANEL

BOULDER ASSOCIATES
5646 MILTON STREET, SUITE 240
DALLAS, TEXAS 75206
214.420.5700

PROJECT P214954.00

SURGCENTER AT NATIONAL HARBOR, LLC DBA HARBORSIDE SURGERY CENTER

251 NATIONAL HARBOR BLVD.
SUITE 200
OXON HILL, MD 20745

ISSUED FOR CONSTRUCTION

DATE 2022.06.03

REVISIONS

#	DESCRIPTION	DATE
3	PRE CONSTRUCTION COORDINATION	06/03/2022
6	ASI#4	7/13/2022
7	DUCTWORK COORDINATION	8/26/2022

RECORD DRAWING

PROFESSIONAL CERTIFICATION. I HEREBY CERTIFY THAT THESE DOCUMENTS WERE PREPARED OR APPROVED BY ME, AND THAT I AM A DULY LICENSED PROFESSIONAL ENGINEER UNDER THE LAWS OF THE STATE OF MARYLAND, LICENSE NO._____, EXPIRATION DATE:_____.

SHEET TITLE

FLOOR PLAN - OVERALL

SHEET NUMBER

A2.10

Appendix 4
Ownership List

Owner	Ownership Share (%)	Address
M2 Orthopedic Partners Holdings, LLC	60.27	5324 2nd Street Boulder, CO 80304
Sameer Nagda, M.D.	5.13	2501 Parkers Lane, Alexandria Va 22306
Kevin Fricka, M.D.	4.73	2501 Parkers Lane, Alexandria Va 22306
Ben Kittredge, M.D.	4.73	6354 Walker Ln STE 300, Alexandria VA 22310
George Branche III, M.D.	4.35	2800 Shirlington Road Arlington Va 22206
William G. Hamilton, M.D.	4.35	2501 Parkers Lane, Alexandria Va 22306
Michael Nathan, M.D.	3.16	2616 Sherwood Hall Lane, Suite 408, Alexandria, VA 22306
Robert Sershon, M.D.	2.80	2800 Shirlington Road Arlington Va 22206
David Weintritt, M.D.	1.99	4660 Kenmore Ave, Suite 1018, Alexandria, VA 22304
Steven Saddler, M.D.	1.97	2800 Shirlington Road Arlington Va 22206
Cassie Root, M.D.	1.58	1715 N George Mason Dr STE 504, Arlington, VA 22205
Corey Wallach, M.D.	1.58	2800 Shirlington Road Arlington Va 22206
Rikesh Gandhi, M.D.	1.32	2800 Shirlington Road Arlington Va 22206
Nigel Azer, M.D.	1.02	2800 Shirlington Road Arlington Va 22206
G. Anderson Engh, M.D.	0.51	2501 Parkers Lane, Alexandria Va 22306
Craig McAsey, M.D.	0.51	2501 Parkers Lane, Alexandria Va 22306
Total Ownership Share	**100.00**	

Appendix 5:
Staff Analysis of the Statistical Projections for Harborside Surgery Center (Entire Facility)

	Staff Analysis - Data per FASF Survey				**Data per CON**						
	Reported				**Actual**		**Projected**				
	CY2018	***CY2019***	***CY2021***	***CY2022***	**CY2022**	**CY2023**	**CY2024**	**CY2025**	**CY2026**	**CY2027**	**CY2028**
Number of Operating Rooms (ORs) (a)	*1*	*1*	*1*	*1*	1	2	2	3	3	3	3
Total Cases (b)	*1148*	*1190*	*1074*	*1140*	1,151	1,846	2,145	2,410	2,710	2,993	3,067
Total Surgical Hours in OR (c)	*84,060*	*86,640*	*81,060*	*80,940*	99,327	159,164	186,130	209,629	237,575	264,144	271,521
Total Surgical Minutes in OR (d=c x 60)	*1,401*	*1,444*	*1,351*	*1,349*	1,655	2,653	3,102	3,494	3,960	4,402	4,525
OR Turnaround Minutes, 25 minutes per case (e = b x 25)	*28,700*	*29,750*	*26,850*	*28,500*	28,775	46,150	53,625	60,250	67,750	74,825	76,675
Total OR Minutes, including Turnaround (f=d+e)	*112,760*	*116,390*	*107,910*	*109,440*	128,102	205,314	239,755	269,879	305,325	338,969	348,196
Total Hours (g=f / 60)	*1879.33*	*1939.83*	*1798.50*	*1824.00*	2,135.03	3,421.91	3,995.92	4,497.98	5,088.75	5,649.48	5,803.27
Optimal Capacity, Hours (h)*	*1,632.00*	*1,632.00*	*1,632.00*	*1,632.00*	1,632.00	3,264.00	3,264.00	4,896.00	4,896.00	4,896.00	4,896.00
Utilization, Percent (i=g/h)	*115.2%*	*118.9%*	*110.2%*	*111.8%*	130.8%	104.8%	122.4%	91.9%	103.9%	115.4%	118.5%
OR Need (j=g/1632)	*1.2*	*1.2*	*1.1*	*1.1*	1.3	2.1	2.4	2.8	3.1	3.5	3.6
Staff Analysis: Surgical Mins per Case (k=d/b)	*73*	*73*	*75*	*71*	*86*	*86*	*87*	*87*	*88*	*88*	*89*
Staff Analysis: Total OR Minutes per Case (l=f/b)	*98*	*98*	*100*	*96*	*111*	*111*	*112*	*112*	*113*	*113*	*114*
Staff Analysis: Permissible OR Minutes (m=h x 60)	*97,920*	*97,920*	*97,920*	*97,920*	*97,920*	*195,840*	*195,840*	*293,760*	*293,760*	*293,760*	*293,760*
Staff Analysis: Minimum Permissible Turnover Time to achieve Optimal Capacity (n=(m-d)/b)	*12*	*9*	*16*	*15*	*-1*	*20*	*5*	*35*	*21*	*10*	*7*
Staff Analysis: Utilization with Minimum Permissible Turnover Time (o=((n x b)+d)/m	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*

**Note: Optimal Capacity is 1,632 hours per year.*

Appendix 6:
Staff Analysis of the Operating Room and Procedure Room Cases at Harborside Surgery Center (Entire Facility)

	Actual		**Curr. Year Projected**	**Projected Years (ending with first full year at full utilization)**				***Staff Analysis***	
	2022	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	***CAGR (5 Yr Period)***	***CAGR (3 Yr Period)***
a. Number of operating rooms (ORs)	1	2	2	3	3	3	3	8.4%	0.0%
● Total Procedures in ORs	4,679	5,360	6,219	6,991	7,851	8,673	8,884	10.6%	8.3%
● Total Cases in ORs (o)	1,151	1,846	2,145	2,410	2,710	2,993	3,067	10.7%	8.4%
● Total Surgical Minutes in ORs**	99,327	159,164	186,130	209,629	237,575	264,144	271,521	11.3%	9.0%
b. Number of Procedure Rooms (PRs)	1	3	3	2	2	2	2	-7.8%	0.0%
● Total Procedures in PRs	2,824	3,167	4,007	4,972	5,250	5,576	5,730	12.6%	4.8%
● Total Cases in PRs (p)	1,081	1,200	1,434	1,758	1,853	1,947	1,995	10.7%	4.3%
● Total Minutes in PRs**	62,026	73,459	91,636	108,350	113,697	120,450	123,781	11.0%	4.5%
Staff Analysis-Total Facility Volume (tfv=o+p)	*2,232*	*3,046*	*3,579*	*4,168*	*4,563*	*4,940*	*5,062*	10.7%	6.7%

Appendix 7:
Staff Analysis of the Revenues (entire facility including proposed project) for Harborside Surgery Center

	CON Data							Staff Analysis	
1. Revenue	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	***CAGR (5 Yr Period)***	***CAGR (3 Yr Period)***
a. Inpatient services									
b. Outpatient services	$82,867,820	$135,756,360	$173,714,825	$201,660,081	$226,654,893	$250,202,290	$257,122,309	13.6%	8.4%
c. Gross Patient Service Revenue	$82,867,820	$135,756,360	$173,714,825	$201,660,081	$226,654,893	$250,202,290	$257,122,309	13.6%	8.4%
d. Allowance for Bad Debt (-)	($15,099)	($263,323)	($296,772)	($390,062)	($437,825)	($482,683)	($495,391)	13.5%	8.3%
e. Contractual Allowance (-)	($69,558,999)	($114,017,154)	($145,728,275)	($169,181,795)	($190,207,367)	($210,028,631)	($215,891,527)	13.6%	8.5%
f. Charity Care (-)			($248,030)	($275,876)	($302,006)	($324,732)	($332,716)		6.4%
g. Net Patient Services Revenue	$13,293,722	$21,475,883	$27,441,748	$31,812,348	$35,707,695	$39,366,243	$40,402,674	13.5%	**8.3%**
h. Other Operating Revenues	$116,512	$159,401	$203,391	$236,122	$265,035	$292,190	$299,882	13.5%	8.3%
i. Net Operating Revenue	$13,410,235	$21,635,284	$27,645,139	$32,048,470	$35,972,730	$39,658,433	$40,702,557	13.5%	8.3%
Test-footing of Net Pat Srvs Rev **(g=c+d+e+f)**	*$13,293,722*	*$21,475,882.96*	*$27,441,747.94*	*$31,812,348.00*	*$35,707,695.00*	*$39,366,244.00*	*$40,402,675.00*	13.5%	8.3%
Test-footing of Net Op Rev **(i=g+h)**	*$13,410,234.69*	*$21,635,284.29*	*$27,645,138.85*	*$32,048,470.00*	*$35,972,730.00*	*$39,658,434.00*	*$40,702,557.00*	13.5%	8.3%
Staff Analysis-Bad Debt as % of Net Op rev	*0.1%*	*1.2%*	*1.1%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	0.0%	0.0%

before Bad Debt Exp (j=d/(d+i))									
Staff Analysis-Gross Revenue per Case (k=c/tfv)	*$37,131.50*	*$44,573.76*	*$48,533.13*	*$48,382.94*	*$49,672.34*	*$50,648.24*	*$50,794.61*	2.6%	1.6%

Appendix 8:
Staff Analysis of the Expenses (entire facility including proposed project) for Harborside Surgery Center

	CON Data							Staff Analysis	
2. Expenses	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	***CAGR (5 Yr Period)***	***CAGR (3 Yr Period)***
a. Salaries, Wages, and Professional Fees (including fringe benefits)	$2,705,517	$3,942,055	$4,595,195	$5,216,653	$5,734,085	$6,023,197	$6,198,313	*9.5%*	*5.9%*
b. Contractual Services	$588,960	$836,770	$1,083,722	$1,203,747	$1,322,792	$1,434,192	$1,468,326	*11.9%*	*6.8%*
c. Interest on Current Debt	$71,765	$973,779	$0	$884,644	$776,320	$667,996	$559,673	*-10.5%*	*-14.2%*
d. Interest on Project Debt	$0	$0	$0	$0	$0	$0	$0		
e. Current Depreciation	$151,344	$1,034,315	$735,004	$735,004	$735,004	$735,004	$735,004	*-6.6%*	*0.0%*
f. Project Depreciation	$0	$0	$0	$14,799	$14,799	$14,799	$14,799		*0.0%*
g. Current Amortization	$4,302,711	$4,302,711	$4,316,151	$4,316,151	$4,316,151	$4,316,151	$4,316,151	*0.1%*	*0.0%*
h. Project Amortization	$0	$0	$0	$0	$0	$0	$0		
i. Supplies	$4,564,749	$8,559,580	$11,505,788	$13,375,611	$15,377,727	$17,278,023	$17,932,304	*15.9%*	*10.3%*
j. Other Expenses	$866,927	$1,210,866	$1,579,795	$1,841,038	$1,923,743	$2,003,818	$2,046,991	*11.1%*	*3.6%*
k. Total Operating Expenses	$13,251,974	$20,860,076	$24,802,953	$27,587,647	$30,200,621	$32,473,181	$33,271,560	*9.8%*	*6.4%*
Test-footing of Op Ex **(k=a+b+c+d+e+f+g+h+i+j)**	***$13,251,974***	***$20,860,076***	***$23,815,656***	***$27,587,646***	***$30,200,621***	***$32,473,180***	***$33,271,560***	*9.8%*	*6.4%*
Test-Only Salaries Source: DI#11, Page 8	$2,124,256	$3,008,612	$3,444,173	$3,929,615	$4,333,799	$4,559,635	$4,696,424	*9.3%*	*6.1%*
*Staff Analysis-Charity Care as % of Op Ex (l=App 11 (e) / k)*100*	*0.0%*	*0.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*		
Staff Analysis-Direct Patient Costs (m=a+b+i+j)	*$8,726,153.76*	*$14,549,270.17*	*$18,764,500.95*	*$21,637,048.86*	*$24,358,346.93*	*$26,739,230.10*	*$27,645,934.01*	*13.7%*	*8.5%*
Staff Analysis-Cost per	*$3,910.02*	*$4,777.06*	*$5,242.50*	*$5,191.23*	*$5,338.23*	*$5,412.80*	*$5,461.46*	*2.7%*	*1.7%*

Case (n=m/tfv)									
Staff Analysis-Cost-To-Charge Ratio (o=n/j)	*0.11*	*0.11*	*0.11*	*0.11*	*0.11*	*0.11*	*0.11*	*0.1%*	*0.1%*

Appendix 9:
Staff Analysis of the Income (entire facility including proposed project) for Harborside Surgery Center

	CON Data							Staff Analysis	
3. Income	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	***CAGR (5 Yr Period)***	***CAGR (3 Yr Period)***
a. Income from Operation	$158,260	$775,208	$2,842,186	$4,460,823	$5,772,109	$7,185,252	$7,430,996	*57.2%*	*18.5%*
b. Non-Operating Income	($902,768)	($675,969)	$0	$0	$0	$0	$0		
c. Subtotal =a+b)	($744,507)	$99,239	$2,842,186	$4,460,823	$5,772,109	$7,185,252	$7,430,996	*137.1%*	*18.5%*
d. Income Taxes	$0	$0	$0	$0	$0	$0	$0		
e. Net Income (Loss) (=c-d)	**($744,507)**	**$99,239**	**$2,842,186**	**$4,460,823**	**$5,772,109**	**$7,185,252**	**$7,430,996**	*137.1%*	*18.5%*
Test-footing of Operating Income F=App 11 (i) – App 12 (k)	*$158,260*	*$775,208*	*$3,829,483*	*$4,460,824*	*$5,772,109*	*$7,185,254*	*$7,430,997*	*57.2%*	*18.5%*
Staff Analysis-Operating Profit Margin (f=a/App 11 (i) %)	*1.2%*	*3.6%*	*13.9%*	*13.9%*	*16.0%*	*18.1%*	*18.3%*	*38.5%*	*9.5%*
Staff Analysis-Normalized EBITDA (g=a+SUM(App 12 c:h))	*$4,684,081*	*$7,086,014*	*$8,880,638*	*$10,411,421*	*$11,614,383*	*$12,919,204*	*$13,056,623*	*13.0%*	*7.8%*