IN THE MATTER OF	*	
	*	
UNIVERSITY OF MARYLAND	*	**BEFORE THE**
	*	
MEDICAL CENTER	*	**MARYLAND HEALTH**
	*	
ADDITION OF PEDIATRIC	*	**CARE COMMISSION**
	*	
HYBRID OPERATING ROOM	*	
	*	
Docket No. 20-24-2445	*	
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Staff Report and Recommendation

March 18, 2021

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I. INTRODUCTION

A. The Applicant

The University of Maryland Medical Center (UMMC), located at 22 South Greene Street in Baltimore City, is an 806-bed general hospital.[1] It is the teaching hospital for the University of Maryland School of Medicine, the second largest general hospital in the state, and the largest and most comprehensive general hospital within the 12-hospital University of Maryland Medical System, Inc. (UMMS).

Currently, UMMC has 23 mixed-use general purpose operating rooms (ORs) and 12 special purpose ORs operating in three locations across the medical center campus; the R. Adams Cowley Shock Trauma Center at the University of Maryland Trauma Center; the Harry and Jeannette Weinberg Building; and the North Hospital Building, which includes the University of Maryland Children's Hospital Pediatric Cardiac Program.[2]

B. The Project

UMMC proposes to expand the capacity of its pediatric cardiac surgical and interventional service line by adding the hospital's second special purpose hybrid pediatric operating room that will serve the University of Maryland Children's Hospital Pediatric Cardiac Program (the Children's Heart Program). Located on the seventh floor of the North Building, the Children's Heart Program has an existing single special purpose hybrid OR, which is outfitted with highly specialized equipment for heart surgeries and cardiac catheterization procedures used in addressing congenital heart issues.

The project will be implemented through a phased-in-place renovation of 7,520 square feet (SF)[3] on the seventh floor of UMMC's north building. The first phase will create space for the new hybrid OR by relocating support services within the existing OR suite and relocating two existing mixed-use general purpose ORs into the vacated support service space. The second phase will involve constructing the proposed hybrid OR in the footprint of the two relocated mixed-use general purpose ORs.

The applicant states that the timeline for project construction includes approximately 11 months to complete Phase One and approximately seven months for Phase Two. (DI #2, pp. 9-10). Upon project completion, the new hybrid OR will be designed to accommodate advanced cardiac catheterization procedures requiring advanced biplane x-ray imaging as well as cardiac surgery cases. Upon project completion, UMMC's special purpose ORs will increase to 13, including two dedicated special purpose hybrid ORs to serve the UMMC Children's Heart Program; the number of mixed-use general purpose ORs will not change. (DI #9, p. 1). The three

[1] Because of the COVID-19 State of Emergency, the Secretary of Health suspended the annual adjustment of licensed acute care hospital bed capacity. Thus, at this time, the licensed acute care hospital bed capacity of general hospitals established in FY 2020 remains in effect for FY 2021, which began on July 1, 2020.

[2] UMMC campus map located at: https://www.umms.org/-/media/files/ummc/for-health-professionals/gme/residency-fellowship/internal-medicine/campus-map--dom-interviews

[3] The total departmental square footage for the surgical suite is 20,800 SF. (DI #2, Exh. 19, Table B).

general-purpose ORs that are currently located on the seventh floor of UMMC's North Building, which currently serve adult and pediatric patients, will be dedicated to pediatric use upon completion of this project.

This project is identified as a component of UMMC's Master Facility Plan to consolidate pediatric surgery and other procedures and create a dedicated pediatric unit on the seventh floor of the north building. After the new hybrid OR is operational, UMMC will renovate and replace the equipment in the existing hybrid OR. Thus, the new hybrid OR will allow the UMMC Children's Heart Program to continue serving its patients during this future upgrade.

The total capital cost of the project is estimated at $9.56 million. The sources of funds for this project include $3.0 million in philanthropy and $6.56 million in cash from operations.

C. Staff Recommendation

Staff recommends approval of the project based on its conclusion that the proposed project complies with the applicable State Health Plan standards, and that the need for the project, its cost effectiveness, and its viability have been demonstrated. Staff also concludes that the project will not have an adverse impact on other providers or the health care delivery system, and will improve access for patients and improve the efficiency of the staff. A summary of the basis for this recommendation with respect to key criteria follows:

Need for the Project

The applicant has demonstrated that case volume increases experienced in recent years have outstripped the capacity of UMMC's single hybrid pediatric operating room. UMMC has one of the two pediatric cardiac programs in Maryland. UMMC has shown that the proposed project will improve the current situation in which patients are experiencing delays in critical treatment, because the single existing hybrid OR's available capacity is in use or out of service for repair and maintenance, down time that increases over time for the room's aging technology. Currently 33% of the cases that would be best performed in the special OR are being scheduled for general ORs, which are not optimally equipped or staffed for pediatric cardiac surgery. Thus, staff believes that the addition of a second hybrid pediatric operating room will improve access for patients and allow for improved staffing efficiency for the hospital.

Patient Safety

The applicant demonstrated that the project will enhance patient safety by increasing utilization of specially trained support staff for these procedures by reducing use of less optimal general purpose ORs, reduce crowding in ORs, and reduce the levels of x-ray exposure for surgical patients, through the installation of new imaging equipment.

Financial Feasibility and Viability

The applicant will pay for the project with a combination of cash and philanthropy. Although the incremental financial impact of the project is a projected loss of about $1.5 million annually, UMMC appears to be well-positioned to subsidize this expansion of service capacity and service upgrade. UMMC will never seek a rate increase related to this project.

Availability of More Cost-Effective Alternatives and Impact

Staff concludes that the project will not have an appreciable impact on costs or charges for surgical services provided by UMMC and will not have a significant negative impact on other hospitals. UMMC operates one of only two specialized programs for pediatric cardiac surgery in Maryland, with the other located at Johns Hopkins Hospital. The project should improve access to needed cardiac procedural and surgical capacity for pediatric patients with congenital heart defects.

Staff also concludes that UMMC has satisfied the applicable State Health Plan standards for this type of project. Staff recommends that any approval of this project be issued with the following condition:

The University of Maryland Medical Center shall provide to the public upon inquiry information concerning charges for the full range of surgical services it provides and shall maintain compliance with applicable laws and regulations regarding the posting of charges.

II. PROCEDURAL HISTORY

A. Record of the Review

Please see Appendix 1, Record of the Review.

B. Interested Parties

There are no interested parties in this review.

C. Local Government Review and Comment

No comments were received from local governmental bodies.

D. Community Support

University of Maryland Medical Center provided letters of support from local officials and persons associated with either UMMC or UMMS who support the need "to build a second pediatric hybrid operating room with biplane technology." (DI #2, pp. 60-61, Exh. 15). These letters came from the following individuals:

- Courtney Agnoli, parent of a UMMC patient
- Robert Barlow M.D., Ph.D., Pediatric Cardiologist, Children's Heart Institute
- Wanda Best, Executive Director, Upton Planning Committee, Inc.
- The Reverend Angela T. Burden
- Eric T. Costello, member, Baltimore City Council, 11th District
- Stephen J. Czinn, M.D., Professor & Chair, Department of Pediatrics, University of Maryland School of Medicine
- Bowyer G. Freeman, D.Min., Senior Pastor, New St. Mark Baptist Church

- The Reverend Dr. Arnold W. Howard, Pastor, Enon Baptist Church
- Christine L. Lau, M.D., Chair, Department of Surgery, University of Maryland School of Medicine
- Karl E. Perry, Principal, Edmondson-Westside High School
- Phyllicia Porter, Council member-elect, Baltimore City County, 10th District
- Mohan Suntha, M.D., President & CEO, University of Maryland Medical System
- Roger W. Voight, M.B., Ch.B., Surgeon-in-Chief, University of Maryland Children's Hospital
- Rev. Tamara E. Wilson, D.Min., Pastor, Nu Season Nu Day Church & Ministries

III. STAFF REVIEW AND ANALYSIS

The Commission is required to make its decision in accordance with the general Certificate of Need review criteria at COMAR 10.24.01.08G(3) (a) through (f). The first of these six general criteria requires the Commission to consider and evaluate this application according to all relevant State Health Plan (SHP) standards and policies.

A. 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 State Health Plan chapters that apply in this review are the Acute Care Hospital Services chapter, COMAR 10.24.10 (Acute Hospital Services Chapter), and COMAR 10.24.11, the General Surgical Services chapter (Surgical Services Chapter).

COMAR 10.24.10 - State Health Plan for Facilities and Services:
Acute Care Hospital Services

COMAR 10.24.10.04A - General Standards.

(1) <u>Information Regarding Charges.</u>
Information regarding hospital charges shall be available to the public. After July 1, 2010, each hospital shall have a written policy for the provision of information to the public concerning charges for its services. At a minimum, this policy shall include:

(a) Maintenance of a Representative List of Services and Charges that is readily available to the public in written form at the hospital and on the hospital's internet web site;

(b) Procedures for promptly responding to individual requests for current charges for specific services/procedures; and

(c) Requirements for staff training to ensure that inquiries regarding charges for its services are appropriately handled.

In its application, UMMC stated that the current list of representative services and charges is available to the public and on the UMMC's website.[4] (DI #2, p. 35). Staff subsequently verified that the UMMC's website includes a page titled "Hospital Charges" with a working link to a PDF that includes a list of representative charges. UMMC stated that its policy requires that it will provide prompt responses to requests for current charges for specific services/procedures. Additionally, the applicant stated that it requires staff training to ensure that inquiries regarding charges for its services are appropriately handled. (DI #2, p. 16).

Staff concludes that UMMC meets this standard.

(2) <u>Charity Care Policy.</u>
Each hospital shall have a written policy for the provision of charity care for indigent patients to ensure access to services regardless of an individual's ability to pay.

(a) The policy shall provide:

(i) Determination of Probable Eligibility. Within two business days following a patient's request for charity care services, application for medical assistance, or both, the hospital must make a determination of probable eligibility.

UMMC states that it provides care to indigent patients, and provided a copy of UMMS Financial Assistance Policy with its application. The policy is posted on UMMC's website. (DI #9, Exh. 21). The policy states that a patient must provide information about family size and income in order to receive a determination of probable eligibility within two business days following a request for charity care services, medical assistance, or both. An application is not necessary to determine probable eligibility, but final determination of eligibility follows completion of a Financial Assistance Application. (DI #9, Exh. 21, p. 6).

(ii) Minimum Required Notice of Charity Care Policy.

1. Public notice of information regarding the hospital's charity care policy shall be distributed through methods designed to best reach the target population and in a format understandable by the target population on an annual basis;
2. Notices regarding the hospital's charity care policy shall be posted in the admissions office, business office, and emergency department areas within the hospital; and
3. Individual notice regarding the hospital's charity care policy shall be provided at the time of preadmission or admission to each person who seeks services in the hospital.

UMMC stated that it provides public notices yearly in local newspapers serving the hospital's target population. (DI #2, p. 17, Exh. 5). UMMC included a copy of its Financial

[4] Available at: https://www.umms.org/ummc/patients-visitors/for-patients/hospital-charges.

Assistance Policy Notice (DI #2, Exh. 6), which it states is posted at patient registration locations, the billing department, the emergency department, in other key patient access areas, and on UMMC's website. This notice is also provided to patients at all registration areas and at the time of preadmission or admission. (DI #2, p. 17).

(b) 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 Health Service Cost Review Commission Community Benefit Report, shall demonstrate that its level of charity care is appropriate to the needs of its service area population.

The HSCRC's Maryland Hospital Community Benefit Report for FY 2019, published in June 2020, reports that UMMC's provision of charity care (almost $23.2 million, equivalent to 1.4% of total operating expenses) ranked in the third quartile for all Maryland hospitals as a percentage of total operating expenses. (DI #2, pp. 18-20).

Staff concludes that the applicant has met the charity care standard.

(3) <u>Quality of Care.</u>
An acute care hospital shall provide high quality care.

(a) Each hospital shall document that it is:

(i) Licensed, in good standing, by the Maryland Department of Health and Mental Hygiene;
(ii) Accredited by the Joint Commission; and
(iii) In compliance with the conditions of participation of the Medicare and Medicaid programs.

The applicant is licensed by the Maryland Department of Health, is accredited by The Joint Commission,[5] and is in compliance with all Medicare and Medicaid conditions of participation. (DI #2, p. 21).

(b) A hospital with a measure value for a Quality Measure included in the most recent update of the Maryland Hospital Performance Evaluation Guide that falls within the bottom quartile of all hospitals' reported performance measured for that Quality Measure and also falls below a 90% level of compliance with the Quality Measure, shall document each action it is taking to improve performance for that Quality Measure.

Staff notes that Paragraph (b) of this standard, as currently written, has become outdated in recent years. Although there is still a Maryland Hospital Performance Evaluation Guide (HPEG), which is the hospital consumer guide component of the MHCC website, the current

[5] UMMC states that its most recent accreditation letter was valid through October 21, 2020. UMMC is due for an onsite survey by The Joint Commission "at any time." (DI # 2, p. 21).

format is different. While quality measures remain a component of that guide, it has been substantially expanded to include many more measures of hospital quality and performance. Moreover, the specific format of the quality measure component of the HPEG no longer consists of a set of measure values that conform with the format of this standard in which each measure is scored as a compliance percentage that can be ranked by quartile. The performance for most of the expanded number of quality measures is now in a comparative context, expressed as "Below Average, Average, or Better than Average." To comply with the spirit of this standard, applicants are asked to identify any "below average" rating and discuss their approach to upgrading performance.

UMMC ranked "Below Average" in ten quality measures in the most recent Maryland Hospital Performance Evaluation Guide. The applicant provided an action plan for each of these quality measures except for two childbirth measures, "Percentage of births (deliveries) that are C-sections" and "How often babies in the hospital are delivered using cesarean section when this is the mother's first birth." The hospital states that it considers the "below average ranking" on the measures as a positive quality indicator consistent with The Joint Commission's encouragement of hospitals to safely reduce cesarean section rates.[6] (DI #2, p. 21).

UMMC provided action plans for the remaining eight Quality Measures in which it was "Below Average**.**" This information is contained in Appendix 8.

Staff concludes that the applicant has provided documentation that its license is in good standing, that it has achieved Joint Commission accreditation, and is in good standing with the Medicare and Medicaid programs. It submitted a performance improvement plan for most of the "below average" HPEG quality measures. Staff recommends that the Commission find that the applicant complies with this standard.

COMAR 10.24.10.04B Project Review Standards

(1) <u>Geographic Accessibility</u>
A new acute care general hospital or an acute care general hospital being replaced…

(2) <u>Identification of Bed Need and Addition of Beds</u>

(3) <u>Minimum Average Daily Census for Establishment of a Pediatric Unit</u>

These three standards are not applicable to this project which does not propose establishment of a new acute care general hospital or relocation and replacement of an acute care general hospital. The project also does not involve an increase in bed capacity not does it proposed establishment of a new pediatric unit.

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6 See, The Joint Commission, "Public Reporting of High Cesarean Rates to Begin in July 2020," Leading Hospital Improvement Blog:
https://www.jointcommission.org/resources/news-and-multimedia/blogs/leading-hospital-improvement/2019/02/public-reporting-of-high-cesarean-rates-to-begin-in-july-2020/.

(4) Adverse Impact

A capital project undertaken by a hospital shall not have an unwarranted adverse impact on hospital charges, availability of services, or access to services. The Commission will grant a Certificate of Need only if the hospital documents the following:

(a) If the hospital is seeking an increase in rates from the Health Services Cost Review Commission to account for the increase in capital costs associated with the proposed project and the hospital has a fully-adjusted Charge Per Case that exceeds the fully adjusted average Charge Per Case for its peer group, the hospital must document that its Debt to Capitalization ratio is below the average ratio for its peer group. In addition, if the project involves replacement of physical plant assets, the hospital must document that the age of the physical plant assets being replaced exceed the Average Age of Plant for its peer group or otherwise demonstrate why the physical plant assets require replacement in order to achieve the primary objectives of the project; and

UMMC will never seek an adjustment to its Global Budget Revenue to account for the additional depreciation expenses that will result from this project.

(b) If the project reduces the potential availability or accessibility of a facility or service by eliminating, downsizing, or otherwise modifying a facility or service, the applicant shall document that each proposed change will not inappropriately diminish, for the population in the primary service area, the availability or accessibility to care, including access for the indigent and/or uninsured.

This standard is not applicable, as the project will not reduce the availability or accessibility of services. On the contrary, it is expected to improve the availability and timely delivery of pediatric cardiac surgery and interventional care.

(5) Cost-Effectiveness

A proposed hospital capital project should represent the most cost effective approach to meeting the needs that the project seeks to address.

(a) To demonstrate cost effectiveness, an applicant shall identify each primary objective of its proposed project and shall identify at least two alternative approaches that it considered for achieving these primary objectives. For each approach, the hospital must:

(i) To the extent possible, quantify the level of effectiveness of each alternative in achieving each primary objective;
(ii) Detail the capital and operational cost estimates and projections developed by the hospital for each alternative; and
(iii) Explain the basis for choosing the proposed project and rejecting alternative approaches to achieving the project's objectives.

(b) An applicant proposing a project involving limited objectives, including, but not limited to, the introduction of a new single service, the expansion of capacity for a single service, or a project limited to renovation of an existing facility for purposes of modernization, may address the cost-effectiveness of the project without undertaking the analysis outlined in (a) above, by demonstrating that there is only one practical approach to achieving the project's objectives.

The applicant states that the proposed project involves a limited objective, the expansion of the capacity of a single service, pediatric cardiac surgery and interventional services. Thus, it asserts that its analysis for this proposed project can be limited to demonstrating that its proposed approach is the only practical one to achieve the objective.

As previously noted, the project is proposed to address pediatric hybrid OR capacity. The location that the applicant chose for the second hybrid OR was driven by the need to locate it adjacent to the existing pediatric hybrid OR, in order to maximize clinical and operational efficiencies and patient safety. UMMC's plan to create a dedicated, pediatric surgical suite with a pre-operative preparation and post-surgical recovery units on this floor was also a factor in the location decision. (DI #2, p. 25).

The project's design will allow the applicant to add one pediatric hybrid OR to its existing surgical suite of four ORs (three mixed-use general purpose ORs and one hybrid OR) within the existing square footage by using space that was originally designed as a sterile processing center, which will be renovated and repurposed as OR space, thus creating the square footage needed for the new pediatric hybrid OR without expanding the overall size of the OR suite. (DI #2, p. 25).

(c) An applicant proposing establishment of a new hospital …

The applicant is not proposing to establish a new hospital or relocate an existing hospital. This section of the standard is not applicable.

Staff concludes that the applicant has met the requirements of this standard.

(6) Burden of Proof Regarding Need

A hospital project shall be approved only if there is demonstrable need. The burden of demonstrating need for a service not covered by Regulation .05 of this Chapter or by another chapter of the State Health Plan, including a service for which need is not separately projected, rests with the applicant.

See the discussion of the need for this project for expansion of OR capacity at the Need standard, COMAR 10.24.11.05B(3), on pages 18 and 19. Staff concludes that the applicant has demonstrated need.

(7) Construction Cost of Hospital Space

The proposed cost of a hospital construction project shall be reasonable and consistent with current industry cost experience in Maryland. The projected cost per square foot of a hospital construction project or renovation project 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. If the projected cost per square foot exceeds the Marshall Valuation Service® benchmark cost, any rate increase proposed by the hospital related to the capital cost of the project shall not include the amount of the projected construction cost that exceeds the Marshall Valuation Service® benchmark and those portions of the contingency allowance, inflation allowance, and capitalized construction interest expenditure that are based on the excess construction cost.

This standard requires a comparison of the project's estimated construction cost with an index cost (i.e., essentially an expected or benchmark cost) derived from the Marshall Valuation Service (MVS) guide. Appendix 5 provides a detailed explanation of the methodology laid out in the MVS guide and how it is used to derive a benchmark value that can be used to assess the appropriateness of new construction costs in a proposed project.

The methodology was developed to allow comparison of new construction projects to a benchmark cost and is of limited use in evaluating the cost of renovation projects. That said, Commission staff calculated an MVS benchmark value of $798.99 per SF for the proposed project. Thus UMMC's projected construction cost of $525.38 per SF is well below the MVS benchmark. Further discussion on this standard is found in Appendix 5. More importantly, the applicant is not and will never seek any adjustment in charges related to the cost of this project.

Staff concludes that the cost estimate is reasonable and consistent with current industry experience in Maryland.

(8) Construction Cost of Non-Hospital Space

The project does not involve changes to non-hospital space. This standard is not applicable.

(9) Inpatient Nursing Unit Space

This standard is not applicable because the project does not involve construction or renovation of inpatient nursing units.

(10) Rate Reduction Agreement

A high-charge hospital will not be granted a Certificate of Need to establish a new acute care service, or to construct, renovate, upgrade, expand, or modernize acute care facilities, including support and ancillary facilities, unless it has first agreed to enter into a rate reduction agreement with the Health Services Cost Review Commission, or the Health Services Cost Review Commission has determined that a rate reduction agreement is not necessary.

This standard is no longer applicable because HSCRC has replaced the rate reduction agreements referenced by this standard with a Global Budget Revenue (GBR) model that may result in adjustments in GBR updates for inefficient hospitals, a policy currently under

development by HSCRC. Commission staff will consider the ongoing validity and/or revision of this standard in its next iteration of the Acute Hospital Services Chapter, COMAR 10.24.10.

(11) Efficiency

A hospital shall be designed to operate efficiently. Hospitals proposing to replace or expand diagnostic or treatment facilities and services shall:

(a) Provide an analysis of each change in operational efficiency projected for each diagnostic or treatment facility and service being replaced or expanded, and document the manner in which the planning and design of the project took efficiency improvements into account; and

(b) Demonstrate that the proposed project will improve operational efficiency when the proposed replacement or expanded diagnostic or treatment facilities and services are projected to experience increases in the volume of services delivered; or

(c) Demonstrate why improvements in operational efficiency cannot be achieved.

UMMC stated that the proposed second pediatric hybrid OR will reduce or eliminate the cancellations that have grown and become more frequent in recent years as the volume and complexity of procedures have increased, affecting its ability to treat patients. The applicant states that one or two procedure cancellations has a "domino effect," affecting other patients' procedures. (DI #2, pp. 28-29).

The applicant also states that the addition of a second pediatric hybrid OR will "enhance cross utilization and more efficient utilization of staff, supplies and equipment, and will provide for more timely communication and responses by physicians and staff serving this patient population." (DI # 2 p.29). UMMC states that increased procedure volume has, on occasion, required pediatric cardiac surgery cases to be moved to UMMC's general purpose ORs, resulting in the need to transport staff, patients, and specialized equipment through the hospital from the pediatric cardiac surgery suite to the main operating suite, a distance described by the applicant as about the length of a city block. The applicant states that if it continues to operate with just one such OR, and continues to rely on the main OR suite's resources for overflow, it will be necessary for them to hire at least two to three additional FTEs to manage the increased volumes. In addition, such a scenario will require the purchase of over $400,000 worth of specialized equipment for the main OR suite. (DI #9, p. 6).

Staff concludes that the addition of a second pediatric hybrid OR will enhance staffing efficiency and reduce cancellations, and thus the applicant meets the efficiency standard.

(12) Patient Safety

The design of a hospital project shall take patient safety into consideration and shall include design features that enhance and improve patient safety. A hospital proposing to replace or expand its physical plant shall provide an analysis of patient safety features included for each facility or service being replaced or expanded, and document the manner in which the planning and design of the project took patient safety into account.

UMMC stated that it took patient safety into consideration when planning this project. The planning of the configuration of the pediatric hybrid ORs a was key part of this consideration. UMMC has planned to relocate two existing non-cardiac ORs in order to build a new pediatric cardiac hybrid OR adjacent to the existing hybrid OR. The proposed relocation will permit the utilization of specially trained support staff for pediatric and adult congenital interventional catheterization and surgical procedural care. Ensuring that specially trained support staff are able to do their jobs efficiently promotes patient safety.

The applicant stated that the existing hybrid OR does not have enough space and the proposed new hybrid OR has been designed to be larger. This will reduce crowding and allow staff to better serve a patient during an operation or procedure and is expected to lead to better outcomes for patients. The design of the new surgical suite also takes patient safety into account by relocating the trash disposal areas away from the workflow areas, providing a cleaner environment and helping to reduce infections.

UMMC also stated that the new hybrid OR will be equipped with a new x-ray system. The new imaging systems reduce the levels of x-ray exposure, which is beneficial for the vulnerable patients being served by UMMC's Children's Heart Program. It states that "[t]he documented reductions in X-ray exposure that occur with use of the latest technology are significant with around 60-80%." (DI #2, pp. 29-30).

(13) <u>Financial Feasibility</u>
A hospital capital project shall be financially feasible and shall not jeopardize the long-term financial viability of the hospital.

(a) Financial projections filed as part of a hospital Certificate of Need application must be accompanied by a statement containing each assumption used to develop the projections.

The applicant provided utilization projections that are consistent with observed historic trends. UMMC's revenue estimates are consistent with utilization projections and are based on its current GBR, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity care provision. Staffing and other expense projections are consistent with utilization projections and based on the hospital's current expenditure levels and reasonably anticipated future staffing levels. (DI #2, p. 31).

Staff concludes that UMMC provided the assumptions it used in developing its projections and has met the requirements of Paragraph (a) of the standard.

(b) Each applicant must document that:

(i) Utilization projections are consistent with observed historic trends in use of the applicable service(s) by the service area population of the hospital or State Health Plan need projections, if relevant;

The applicant provided utilization projections that are consistent with observed historic trends. (DI # 2, p. 31, Exh 1, Tables F and I). Staff concludes that UMMC has met the requirements of Subparagraph (b)(i) of the standard.

(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 hospital or, if a new hospital, the recent experience of other similar hospitals;

UMMC states that the revenue and expense projections are based on its current Global Budget Revenue, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity care provision. (DI #2, p. 31; Exh. 1, Tbl. G-H). Staff concludes that UMMC has met the requirements of Subparagraph (b)(ii) of the standard.

(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 hospital, or, if a new hospital, the recent experience of other similar hospitals; and

UMMC's assumptions indicate that the staff and other expense projections are consistent with utilization projections and based on current expenditure levels and reasonably anticipated future staffing levels as experienced by UMMC. (DI #2, p. 31; Exh 1, Tbl L). For these reasons, staff concludes that UMMC has met the requirements of Subparagraph (b)(iii) of the standard.

(iv) The hospital will generate excess revenues over total expenses (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 or less of initiating operations with the exception that a hospital may receive a Certificate of Need for a project that does not generate excess revenues over total expenses even if utilization forecasts are achieved for the services affected by the project when the hospital can demonstrate that overall hospital financial performance will be positive and that the services will benefit the hospital's primary service area population.

UMMC projects an increase in expenses related to additional staffing that will support the new hybrid OR when it opens in FY 2023. However, because the hospital is not seeking a capital-related Global Budget Revenue modification from the Health Services Cost Review Commission, the applicant projects no incremental revenue resulting from the project. The marginal financial impact of the project is a reduction in the applicant's operating margin of about $1.46 million. (DI #2. p. 31; Exh. 1, Tbls. J-K). Despite that incremental loss, UMMC projects a healthy bottom line for its entire facility. (DI #2, p. 31; Exh. 1, Tbl. G-H).

The applicant also stated that the proposed project will benefit UMMC's service area population by ensuring the facility provides timely care to pediatric patients in need of cardiac surgery and pediatric and adult patients in need of cardiac catheterization services. (DI #2, pp. 31-32).

Staff concludes that UMMC complies with the standard.

(14) Emergency Department Treatment Capacity and Space
(15) Emergency Department Expansion

Neither of these standards is applicable. The project does not involve changes to the hospital's emergency department facilities.

(16) Shell Space

The project does not include construction of shell space. This standard is not applicable.

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

10.24.11.05A General Standards.

COMAR 10.24.11, the General Surgical Services Chapter of the State Health Plan, guides CON reviews involving non-specialized surgical facilities and services which, in this context, are all surgical facilities and services with the exception of cardiac surgery and organ transplantation surgery. While this project involves addition of an operating room used to provide cardiac surgery, staff determined that it was appropriate to use the Surgical Services Chapter in review of this application. A hospital applicant is required to address all standards applicable to its proposed project in both the Acute Hospital Services Chapter and the Surgical Services Chapter, which provides, at COMAR 10.24.11, that "[a] hospital is not required to address standards in this Chapter that are completely addressed in its responses to the standards in [Acute Hospital Services] Chapter …."

UMMC currently has 23 general purpose ORs and 12 special purpose ORs (35 total). Through relocation, renovation, and construction the applicant intends to add one special purpose OR for a total of 13 special purpose and 36 total ORs.

The standards in the General Surgical Services Chapter, COMAR 10.24.11, that duplicate standards in the previously discussed Acute Care Hospital Services Chapter, COMAR 10.24.10, are addressed in preceding sections of this report:

COMAR 10.24.10.04A(2) Charity Care Policy;[7]
COMAR 10.24.10.04B(7) Construction Costs;[8]
COMAR 10.24.10.04B(12) Patient Safety;[9] and
COMAR 10.24.10.04B(13) Financial Feasibility.[10]

[7] See discussion, *supra*, at p. 5.
[8] See discussion, *supra*, at p. 9.
[9] See discussion, *supra*, at p. 12.
[10] See discussion, *supra*, at p. 12

The analysis of the above standards, completed in discussion of the Acute Hospital Services Chapter will not be repeated in the discussion of comparable standards in the Surgical Services Chapter.

(1) <u>Information Regarding Charges</u>.

Information regarding charges for surgical services shall be available to the public.

(a) A physician outpatient surgery center, ambulatory surgical facility, or a general 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.

As previously stated in consideration of COMAR 10.24.10.04A(1), UMMC stated that the current list of representative services and charges for both hospital charges and for surgical services is available to the public and on the UMMC website.[11] (DI #2, p. 35). Staff subsequently verified that UMMC's website includes a page titled "Hospital Charges" with a working link to a PDF that includes a list of representative charges and for both inpatient and outpatient surgical cases and/or services at UMMC.

(b) 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.

The applicant also states that it is unaware of any complaints to the Consumer Protection Division in the Office of the Attorney General of Maryland or to the Maryland Insurance Administration concerning its provision of information regarding charges to the general public. (DI #18).

(c) Making this information available shall be a condition of any CON issued by the Commission.

The applicant states that it "acknowledges and agrees that making this information available is a condition of any CON issued by the Commission." (DI #2, p. 35).

Staff concludes that UMMC satisfies each paragraph of this standard, and recommends that any approval of this project be issued with the following condition:

The University of Maryland Medical Center shall provide to the public upon inquiry information concerning charges for the full range of surgical services it

[11] Available at: https://www.umms.org/ummc/patients-visitors/for-patients/hospital-charges. and for both inpatient and outpatient surgical services at https://www.umms.org/ummc/-/media/files/ummc/patients-and-visitors/ummc-mhcc-reporting-by-product-lines-fy20-ytd-jan-2.pdf?upd=20201027122115&la=en&hash=4A26A6B3AAF3FD104D07AFA697373CB62CF6EBBA.

provides and shall maintain compliance with applicable laws and regulations regarding the posting of charges.

.05A(2) Information Regarding Procedure Volume.

A hospital, physician outpatient surgery center, or ASF shall provide to the public upon inquiry information concerning the volume of specific surgical procedures performed at the location were an individual has inquired. A hospital, POSC, or ASF shall provide the requested information on surgical procedure volume for the most recent 12 months available, updated at least annually.

UMMC affirmed that it will provide information regarding the volume of specific surgical procedures performed at the facility for the most recent 12 months to any member of the public upon inquiry and that it will update this information at least annually. (DI# 2, p. 36).

Staff concludes that UMMC complies with this standard.

Standards .05A(4) Quality of Care, .05A(5) Transfer Agreements, .05B(4) Design Requirements, and .05B(5), Support Services

Among the remaining applicable standards are several that prescribe policies, facility features, and staffing and/or service requirements that an applicant must meet, or agree to meet prior to first use. Staff reviewed the CON application and confirmed that the applicant provided information and affirmations that demonstrate full compliance with these standards:

.05A(4) Quality of Care
.05A(5) Transfer Agreements
.05B(4) Design Requirements, and
.05B(5) Support Services.

In responding to these standards, staff notes that the applicant:

- Is licensed by the Maryland Department of Health, is accredited by The Joint Commission, and is in compliance with all Medicare and Medicaid conditions of participation;
- Has transfer agreements with other hospitals that comply with the requirements of Maryland Code, Health-General § 19-308.2 and the Maryland Department of Health's regulations implementing this provision;
- Designed its proposed project in compliance with Section 2.2 of the FGI Guidelines, as stated in a letter from Miguel Pascale, the project architect; and
- Agreed to provide all laboratory, radiology, and pathology support services as needed by patients.

The text of these standards and location of the documentation of compliance are attached as Appendix 2.

B. PROJECT REVIEW STANDARDS. The standards in this section govern reviews of Certificate of Need applications and requests for exemption from Certificate of Need review involving surgical facilities and services. An applicant for a Certificate of Need or an exemption from Certificate of Need shall demonstrate consistency with all applicable review standards.

(1) Service Area.

An applicant proposing to establish a new hospital providing surgical services or a new 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.

The applicant proposes to expand the number of ORs in its existing facility by adding one special purpose pediatric hybrid OR that will be dedicated to serving the UMMC Children's Heart Program. The service area of the Children's Heart Program was determined by identifying and ranking the zip code areas comprising the top 85 percent of discharges, by area of origin, for pediatric and adult congenital cardiac surgery and pediatric catheterization patients from FY 2017 to FY 2019. (DI #2, p. 42).

The applicant described this 85% relevance service area for the UMMC Children's Heart Program. The map that the applicant provided can be found in Appendix 3.

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

This standard is not applicable since UMMC is not seeking to establish a new or replacement facility.

(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;

(b) 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

(c) 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 .07 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.

UMMC states that the proposed pediatric hybrid operating room is a special purpose operating room[12] that will serve the UMMC Children's Heart Program and be used to perform surgeries to treat congenital heart issues as well as cardiac catheterization procedures. It states that these programs require "highly specialized equipment not available for infants and children anywhere else in the facility." (DI #2, p. 4). Among that equipment is biplane imaging equipment that requires space for an equipment control room from which the imaging equipment is operated during a procedure. The space must be large enough to accommodate moveable equipment used to provide anesthesia as well as a range of equipment that is regularly called upon although not stationed in the OR (e.g., perfusion and echocardiography machines and ventricular assist devices, among others). (DI #9, p. 8).

The Surgical Services Chapter provides that the optimal capacity and need for a special purpose operating room are best determined on a case-by-case basis, based on information provided by an applicant that describes; the population or facility need, or both, for each special purpose operating room; the documented demand for each special purpose operating room; and any unique operational requirements related to the special purpose for which the operating room will be used.

UMMC first addressed the need for this special purpose pediatric hybrid OR by documenting the growth in demand for its services and the projected population growth in the Children's Heart Program Service Area.

Demand for and use of the pediatric hybrid OR has increased significantly

UMMC states that, between FY 2017 and FY 2020, the number of pediatric cardiac congenital surgical cases doubled, from 140 to 279. Simultaneously the number of cardiac catheterizations during the same time period fell by 18% due to the growing surgical case volume performed in the hybrid OR, which decreased the room's availability for performing cardiac catheterization procedures. (DI #2, p. 46).

[12] A special purpose operating room is defined in COMAR 10.24.11.08B(30) as "a sterile operating room that is dedicated for a specific purpose or surgical specialty and in which space, equipment, or other factors limit its use to a narrow range of surgical procedures."

Table III-1 UMMC's Hybrid OR Pediatric Congenital Cardiac Surgical and Interventional Cases

Procedure	Historic Case Volume				% change	Projected Volumes**					% increase
	FY17	FY18	FY19	FY 20*		FY 21	FY 22	FY 23	FY 24	FY 25	
Cardiac Surgery	140	149	225	279	99.3%	280	281	282	283	285	1.8%
Cardiac Catheterization	205	183	174	168	-18.0%	169	169	170	170	171	1.2%
Total Combined Cases	345	332	399	447	29.6%	449	451	452	454	456	1.6%

**Assumes population growth rate of 0.4% annually or 1.92% for the population residing in UMMC service area
DI #2, Table 4, p. 47.

Over the same time period, UMMC's total minutes for pediatric congenital cardiac surgical and interventional cases grew from 97,000 total minutes in 2017 to almost 140,000 minutes in 2020, a 44% increase. Minutes per case over that period grew from about 282 to 312 (includes a 61 minute room turnaround time). (DI #2, p. 48).

Cases delayed or moved to general ORs

UMMC's Children's Heart Program generally performs its surgical cases and interventional cases in the existing special purpose hybrid OR. When the existing hybrid OR is unavailable because it is being used or its equipment is out of service, procedures must be delayed or moved to the general purpose ORs in the main hospital building.

The applicant states that this is occurring with greater frequency. In the three years between 2017 and 2019 such transfers occurred 213 times; however, in FY 2020, 148 of the 447 Children's Heart Program cases, 33%, had to be moved to UMMC's general purpose ORs because the existing hybrid OR was unavailable. UMMC asserts that these ORs are not as well equipped or staffed for pediatric cases, but instead employ equipment, supplies, and staff suited for adult patients.

UMMC states that "[i]t can take several minutes to transport the pediatric patient and appropriate pediatric equipment, supplies, and support staff to this alternative location. Time is critical for many of these patients and the additional transport and response time can negatively affect the patient's outcome, especially if additional equipment or supplies are required mid-procedure." (DI # 2, p.50).

The applicant notes that, when the existing hybrid OR is unavailable for a pediatric interventional procedure, the procedure must be delayed or even cancelled because as it is the only room with equipment capable of producing high quality imaging for small, pediatric congenital patients. Such delay may permit progression of the disease and possibly increase if the patient has to be treated at a more advanced stage of the disease.

UMMC anticipates that, once the new hybrid OR opens, capacity issues will be resolved, reducing or eliminating the program's current need to transfer cases to UMMC's general purpose ORs. UMMC will use both hybrid ORs for cardiac interventional catheterizations, cardiac

surgical, and hybrid cases. (DI #2, p. 50). Because the new hybrid OR will be larger than the existing one, and will have state-of-the-art equipment, it will use the new hybrid OR as the primary operating room to serve cardiac interventional procedures and hybrid procedures, while the existing hybrid OR will be the primary room for the cardiac surgical cases. (DI # 2, pp. 48 - 50).

The applicant states that the addition of the second hybrid OR will enable the hospital to meet the demand and need for cardiac interventional catheterization and cardiac surgical procedures. It expects that it will not have to delay or cancel procedures, or transfer pediatric surgical cases to the second floor of the Weinberg Building. (DI #2, p. 50). Expanding the surgical services will help to centralize the the Children's Heart Program's special equipment and trained staff in a consolidated area and, eventually, the entire OR suite.

The applicant states that when the second hybrid OR comes on line, it will use both hybrid ORs for cardiac interventional catheterizations, cardiac surgical, and hybrid cases. (DI #2, p. 50). UMMC states the new hybrid OR will be larger than the existing hybrid OR, and will have the state-of-the-art equipment. The hospital will use the new hybrid OR as the primary operating room to serve cardiac interventional procedures and hybrid procedures, while also serving a portion of the pediatric cardiac surgery cases. The existing hybrid OR will be the primary room for the cardiac surgical cases, since this room is smaller and will have imaging equipment that is not as advanced as the new hybrid OR.

Summary

Staff concludes that UMMC has demonstrated the need for this special purpose operating room and has met the requirements of this standard.

(9) Impact.

(a) **An application to establish a new ambulatory surgical facility shall**

This standard is not applicable. The application does not involve establishment of a new ambulatory surgical facility.

(10) Preference in Comparative Reviews.

This standard is not applicable because this review is not part of a comparative review.

B. Need

COMAR 10.24.01.08G (3)(b) 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.

See the preceding review of the Need standard, Minimum Utilization for Expansion of An Existing Facility, page 18. This constitutes an "applicable need analysis in the State Health Plan."

C. Availability of More Cost-Effective Alternatives

COMAR 10.24.01.08G(3)(c) 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.

Project Objectives

As was addressed under the Cost-Effectiveness standard of the Acute Hospital Services Chapter, UMMC explained that this project is limited to the single objective of expanding the capacity of its pediatric cardiac surgical and interventional service by adding a second pediatric hybrid OR, and that it plans to locate the second OR adjacent to the existing pediatric hybrid OR in order to maximize clinical and operational efficiencies and patient safety. (DI #2, p. 58). UMMC examined an alternative design that would locate the second hybrid OR in the space to which the two mixed-use general purpose ORs are being moved in order to create space for the second hybrid OR, which would obviate the need to relocate them. However UMMC found that the configuration of the existing mechanical infrastructure limited the available space, making it insufficient for the new equipment and functionality needed for the new hybrid OR. (DI # 9, p.12).

Providing the Service through Alternative Existing Facilities…

UMMC notes that it is one of only two pediatric cardiac heart programs in the State of Maryland.[13] The applicant explained that many of the patients and families it serves are served by the program over a period of years, and over a lifetime for those patients with congenital heart issues, and that the current project is aimed at better serving its existing patient base. UMMC asserts that, ultimately, it is the patients' choice which program they choose. (DI #9, pp. 11-12).

…or Through Population-Health Initiatives that Would Avoid or Lessen Hospital Admissions.

UMMC states that, although it is consistently engaged in population health initiatives aimed at improving the overall health and outcomes of its service area population, such population health initiatives do not substantially reduce the incidence of congenital cardiac anomalies that require surgical and interventional treatment. UMMC notes that the proposed project will provide the applicant with the surgical capacity that is necessary to continue to treat these patients whose conditions cannot be managed by such population health initiatives. (DI #2, p. 58).

Summary

[13] The other program is The Blalock-Taussig-Thomas Pediatric and Congenital Heart Center at Johns Hopkins Children's Center. Further information is available at: https://www.hopkinsmedicine.org/heart_vascular_institute/specialty_areas/pediatric-and-congenital-heart-center/.

Staff concludes that UMMC adequately examined the limited alternatives for meeting its goal to expand the capacity of its pediatric cardiac surgical and interventional services to increase timely access to those services, and recommends that the Commission find that the applicant has demonstrated the cost-effectiveness of the proposed project.

D. Viability of the Proposal

COMAR 10.24.01.08G(3)(d) The Commission shall consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project within the time frames set forth in the Commission's performance requirements, as well as the availability of resources necessary to sustain the project.

Availability of Resources to Implement the Proposed Project

This project will cost approximately $9.56 million. The applicant will allocate about $6.56 million in cash from its operating budget and $3 million will be funded through philanthropy, which UMMC "has already received from a grateful patient donor." (DI #9, p. 4).

Availability of Resources to Sustain the Proposed Project

UMMC projects that the incremental impact of this project will be a reduction of about $1.5 million in income from operations as the additional hybrid OR will generate additional staffing costs but is not projected to add revenue. Despite this incremental loss, UMMC will continue to generate a substantial margin and is well positioned to support this incremental cost. (DI #2, pp. 59-61; Table K). As is standard practice in a hospital CON review, Commission staff sought an opinion regarding the financial feasibility and viability of the project from HSCRC staff. HSCRC staff wrote:

> Upon review of the statistical and financial information provided in the CON [application] and subsequent completeness responses, it was noted that the project's projected P&L reflects the incurrence of $1.5M in incremental operating expenses (all of which was labor) with no incremental revenue to cover them. Therefore, this project yields a projected $1.5M operating loss per year. Additionally, UMMC neither requests nor projects rate relief in the CON. As per review of the audited financial statements, UMMC had an Operating Profit for FY 2020 of $92.6M; therefore, it is apparent that UMMC can absorb the projected loss without any material adverse impact upon its performance. (DI #17, pp. 1-2)

Community Support

The applicant provided letters expressing support for this project from the members of the community, including leaders of the University of Maryland Medical System, current UMMC clinicians, Baltimore City elected officials, faith and community leaders, and parents of patients. (DI #2, pp. 60-61).

Meeting Staffing and Performance Requirements

Currently, UMMC's Children's Heart Program employs 14.6 full-time equivalent (FTE) staff. (DI #9, Table 9, p. 13). Upon project completion, the applicant expects to hire an additional 16.0 FTE staff at a total cost of almost $1.5 million. (DI #9, Exh. 19, Table L). UMMC does not anticipate having difficulty in recruiting the required additional staff.

UMMC demonstrated knowledge of the process required to meet the applicable performance requirements. The applicant provided a schedule for implementing the project in conformance with the performance requirement deadlines. (DI #2, p. 60).

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.

UMMC provided the following information regarding its performance on Certificates of Need issued to it since 2000:

- Certificate of Need issued in September 2006 for the construction of an ambulatory care center and parking garage. UMMC relinquished the CON after completion of the parking garage;

- Certificate of Need issued in March 2010 to expand trauma, critical care, and emergency services. UMMC completed the approved project and complied with the conditions of the Certificate of Need;

- Certificate of Need issued in May 2019 to expand its inpatient child behavioral health unit by establishing an eight-bed adolescent inpatient behavioral health unit in renovated space. The project is underway and UMMC expects to complete this expansion project in compliance with the terms of the CON; and

- Certificate of Need issued in August 2020 for a building addition and renovations primarily for consolidatrion of cancer center services. This project is underway and UMMC expects to complete the project in compliance with the terms and conditions of the CON. (DI #2, p. 62).

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

The applicant does not anticipate that the proposed project will impact any other existing health care providers. Recently, the UMMC Children's Heart Program has experienced volume growth partially due to provider losses in the only other congenital heart program in Maryland. The applicant expects that the resulting market share shift will be maintained by UMMC going forward but estimates that future growth beyond FY 2020 to be based on growth in the service area population. (DI #2, p. 63).

Impact on access to this health care service

The applicant anticipates that the addition of a new pediatric hybrid OR will resolve its current capacity issues, thereby reducing the program's current delays and the need to use UMMC's main OR suite for the pediatric cases best suited for the specialized OR. The applicant states that this change will "ensure more timely access to cardiac catheterization and cardiac surgical services for its service area population." (DI #2, p. 63).

Impact on costs to the health care delivery system

UMMC does not expect that this project will cause any significant impact on costs related to the health care delivery system. UMMC has confirmed that it will not ever seek an adjustments in revenue related to the project. UMMC stated that, beginning in FY 2023, there will be a slight increase in charges due to incremental staffing increases related to this project, as described in the Applicant's response to the Financial Feasibility Standard at COMAR 10.24.10.04B(13) and 10.24.11.05B(8). (DI #2, pp. 63-64).

IV. SUMMARY AND STAFF RECOMMENDED DECISION

Based on its review of the proposed project and the project's compliance with the applicable review criteria and standards, Commission staff concludes that the project complies with the applicable standards in both the Acute Hospital Services Chapter and the Surgical Services Chapter of the State Health Plan. The applicant has demonstrated the need for the project, the cost-effectiveness of the project, the viability of the project, and the positive impact of the project on access to this service.

Accordingly, staff recommends that the Commission **APPROVE** the University of Maryland Medical Center's application for a CON to to expand the capacity of its pediatric cardiac surgical and interventional service line by adding one pediatric cardiac hybrid operating room that will serve the Children's Hospital Pediatric Cardiac Program with the following condition:

> The University of Maryland Medical Center shall provide to the public upon inquiry information concerning charges for the full range of surgical services it provides and shall maintain compliance with applicable laws and regulations regarding the posting of charges.

IN THE MATTER OF	*	
	*	
UNIVERSITY OF MARYLAND	*	**BEFORE THE**
	*	
MEDICAL CENTER	*	**MARYLAND HEALTH**
	*	
ADDITION OF PEDIATRIC	*	**CARE COMMISSION**
	*	
HYBRID OPERATING ROOM	*	
	*	
Docket No. 20-24-2445	*	
	*	

* *

FINAL ORDER

Based on the analysis in the Staff Report and Recommendation, it is, this 18th day of March, 2021:

ORDERED, that the application by the University of Maryland Medical Center for a Certificate of Need to renovate its pediatric hybrid cardiac operating room suite, adding one pediatric hybrid operating room and replacing two general purpose operating rooms, at an estimated project cost of $9,555,000, is hereby **APPROVED,** subject to the following condition:

> The University of Maryland Medical Center shall provide to the public upon inquiry information concerning charges for the full range of surgical services it provides and shall maintain compliance with applicable laws and regulations regarding the posting of charges.

MARYLAND HEALTH CARE COMMISSION

APPENDIX 1

RECORD OF THE REVIEW

Docket Item #	Description	Date
1	MHCC acknowledges receipt of Letter of Intent.	10/6/20
2	Dana Farrakhan submits on behalf of University of Maryland Medical Center (UMMC) a Certificate of Need (CON) application for a new hybrid OR.	11/13/20
3	MHCC acknowledges receipt of CON application.	11/24/20
4	Staff requests *Baltimore Sun* publish notice of receipt of CON application.	11/24/20
5	Staff requests *Maryland Register* publish notice of receipt of CON application.	11/24/20
6	*Baltimore Sun* sends notice of receipt of CON application as published in the *Baltimore Sun.*	11/24/20
7	Commission staff submits request for completeness and additional information.	12/14/20
8	Mallory Regenbogen, Esq. requests on behalf of UMMC, and MHCC grants extension, to file completeness information.	12/21/20
9	Thomas C. Dame, Esq. submits response to request for additional information.	1/8/21
10	Commission staff informs UMMC that formal start of review will be 2/12/21 and submits request for additional information.	1/29/21
11	Commission staff requests *Baltimore Sun* publish notice of formal start of the review.	1/29/21
12	Commission staff requests *Maryland Register* publish notice of formal start of the review.	1/29/21
13	*Baltimore Sun* sends notice of receipt of notice of formal start of review as published in the *Baltimore Sun.*	2/2/21
14	Commission staff requests comments regarding local health planning from Baltimore City.	2/9/21
15	Mallory Regenbogen submits response to January 29, 2021 request for additional information.	2/17/21
16	Commission staff submits request for HSCRC comments on UMMC project.	2/22/21
17	Katie Wunderlich and Jerry Schmith, Health Services Cost Review Commission, submits HSCRC staff's memorandum regarding its review and opinion of the University of Maryland Medical Center's CON application.	2/24/21
18	Commission staff requests additional information and Mallory Regenbogen responds on behalf of the applicant	3/4/21

APPENDIX 2

EXERPTED CON STANDARDS FOR GENERAL SURGICAL SERVICES FROM STATE HEALTH PLAN CHAPTER 10.24.11

Each of these standards prescribes policies, services, staffing, or facility features necessary for CON approval that MHCC staff have determined the applicant has met. Also included are references to where in the application or completeness correspondence the documentation can be found.

STANDARD	**APPLICATION REFERENCE (Docket Item #)**
.05A(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. (b) A hospital shall document that it is accredited by the Joint Commission. (c) An existing ambulatory surgical facility or POSC 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 agency recognized by the Centers for Medicare and Medicaid as acceptable for obtaining Medicare certification. (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 POSC, as applicable, compares on these quality measures to other facilities that provide the same type of specialized services in Maryland. (d) A person proposing the development of an ambulatory surgical facility shall demonstrate that the proposed facility will: (i) 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; and (ii) Obtain accreditation by the Joint Commission, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities within two years of initiating service at the facility or voluntarily suspend operation of the facility.	DI #2, p. 21

(e) An applicant or a related entity that currently or previously has operated or owned a POSC or ambulatory surgical facility, in Maryland or outside of Maryland, in the five years prior to the applicant's filing of a request for exemption request to establish an ASF, shall address the quality of care at each location through the provision of information on licensure, accreditation, performance metrics, and other relevant information.	
.05A(5) <u>Transfer Agreements.</u> (a) Each ASF shall have written transfer and referral agreements with hospitals capable of managing cases that exceed the capabilities of the ASF. (b) Written transfer agreements between hospitals shall comply with the Department of Health regulations implementing the requirements of Health-General Article, 19-308.2. (c) Each ASF shall have procedures for emergency transfer to a hospital that meet or exceed the minimum requirements in COMAR 10.05.05.09.	DI #2, p. 40
.05B(4) <u>Design Requirements</u>. Floor plans submitted by an applicant must be consistent with the current Facility Guidelines for Design and Construction of Health Care Facilities (FGI Guidelines): (a) A hospital shall meet the requirements in current Section 2.2 of the FGI Guidelines. (b) An ASF shall meet the requirements in current Section 3.7 of the FGI Guidelines. (c) Design features of a hospital or ASF 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.	DI #2, p. 51, Exh. 13
.05B(5) <u>Support Services</u>. Each applicant shall agree to provide laboratory, radiology, and pathology services as needed, either directly or through contractual agreements. .	DI #2, p. 51

APPENDIX 3

ZIP CODES FOR TOP 85% OF PATIENT VOLUME

Zip Code	Cases per Zip Code
21239	54
21221	37
21040	37
21229	36
21220	36
21601	32
21206	31
21074	30
21060	30
21225	29
21234	28
21244	27
21212	26
21030	26
21227	25
21740	23
20743	22
21222	21
21207	21
21228	20
21218	19
21001	19
21217	19
20602	18
21085	18
21214	17
21215	17
21403	16
21009	16
21223	16
21237	16
21144	16
21784	15
21122	15
21032	15
21061	15
21213	14
20778	14
21204	13
20110	13
21133	13
21205	12
21014	12
21401	11
21202	11
20723	11

21901	10
20774	10
21117	10
21236	9
21613	9
20640	9
21921	9
21157	9
21211	9
21209	8
21162	8
21076	8
21045	8
21201	8
20720	8
21632	8
21075	8
21136	8
21804	7
20706	7
21713	7
21216	7
20794	7
21146	7
21208	6
21078	6
20715	6
21210	6
21787	6
21042	6
17315	6
21811	6
21224	6
21773	5
21230	5
20020	5
20871	5
21640	5
20874	5
20721	5
18103	5
21044	4
21015	4
21701	4
21102	4
20769	4
21114	4

21286	4
20852	4
21742	4
21128	4
20111	4
Total	**1318**

APPENDIX 4

PROJECT FLOOR PLANS

APPENDIX 5

MARSHALL VALUATION SERVICE REVIEW

Appendix 5
MHCC Staff Calculation of the MVS Benchmark

The Marshall Valuation System – what it is and how it works

In order to compare the cost of a proposed construction project to that of similar projects as part of a cost-effectiveness analysis, a benchmark cost is typically developed using the Marshall Valuation Service (MVS). MVS cost data includes the base cost per square foot for new construction by type and quality of construction for a wide variety of building uses.

The base cost reported in the MVS guide are based on the actual final costs to the owner and include all material and labor costs, contractor overhead and profit, average architect and engineering fees, nominal building permit costs and processing fees or service charges and normal interest on building funds during construction. It also includes: normal site preparation costs including grading and excavation for foundations and backfill for the structure; and utilities from the lot line to the structure figured for typical setbacks.

The MVS costs do not include costs of buying or assembling land, piling or hillside foundations (these can be priced separately), furnishings and fixtures not found in a general contract, general contingency set aside for some unknown future event such as anticipated labor and material costs increases. Also not included in the base MVS costs are site improvements such as signs, landscaping, paving, walls, and site lighting. Offsite costs such as roads, utilities, and jurisdictional hook-up fees are also excluded from the base costs.[14]

MVS allows staff to develop a benchmark cost using the relevant construction characteristics of the proposed project and the calculator section of the MVS guide. In developing the MVS benchmark costs, the base costs are adjusted for a variety of factors. The MVS cost data includes the base cost-per-square-foot for new construction by type and quality of construction for a wide variety of building uses including general hospitals. The MVS guide also includes a variety of adjustment factors, including adjustments of the base costs to the costs for the latest month, the locality of the construction project, as well as factors for the number of building stories, the height per story, the shape of the building (such as the relationship of floor area to perimeter), and departmental use of space. The MVS guide identifies costs that should not be included in the MVS calculations. These exclusions include costs for buying or assembling land, making improvements to the land, costs related to land planning, discounts or bonuses paid for through financing, yard improvements, costs for off-site work, furnishings and fixtures, marketing costs, and funds set aside for general contingency reserves.[15]

The MVS methodology does not offer data for renovation projects; thus, any effort to compare proposed renovation costs to a benchmark can only be made to the benchmarks for new construction. (In general, the MVS benchmarks are typically much higher than the costs estimated by applicants for the renovation portion of projects.) Thus, UMMC's MVS benchmark developed

[14] Marshall Valuation Service Guidelines, Section 1, p 3 (February 2020).
[15] *Id.*

for the renovation portion of the project is much higher than UMMC's estimated costs of $525.38 per SF for the proposed renovations.

Developing the MVS Benchmark Cost per Square Foot for the Proposed Project

MHCC staff performed an independent analysis to arrive at the MVS benchmark value calculated for the proposed project. In this project UMMC proposes to renovate 7,520 SF within an existing surgical suite located on the 7th floor of the North Building. Commission staff arrived at an MVS value of $798.99 per SF. Commission staff used the base cost for a good quality, Class A construction for a general hospital. MHCC staff used the MVS figures available as of September 2020.

Table 1: Calculation of Marshall Valuation Service Benchmark
For UMMC pediatric hybrid OR

Type Structure	Phase One	Phase Two	Total
Class	A	A	A
Quality	Good	Good	Good
Floors	1	1	1
Square Footage	4,320	3,200	7,520
Average Perimeter	468	232	560
Weighted Average Wall Height	12	12	12
Stories	1	1	1
Average Area Per Floor	4,320	3,200	7,520
Base Cost	398	398	398
Adjusted Base Cost	$ 398.00	$ 398.00	$ 398.00
Adjustment for Dept. Cost Differential	1.89	1.89	1.89
Gross Base Cost	$ 752.22	$ 752.22	$ 752.22
Perimeter Multiplier	1.128704	1.035512	1.041344
Height Multiplier	1	1	1
Multi-story Multiplier*	1	1	1
Multipliers	1.128704	1.035512	1.041344
Refined Square Foot Cost	$ 849.03	$ 778.93	$ 783.32
Adjusted Refined Square Foot Cost	$ 849.03	$ 778.93	$ 783.32
Current Cost Modifier	1.02	1.02	1.02
Local Multiplier	1	1	1
CC & Local Multipliers	1.02	1.02	1.02
MVS Building Cost Per Sq Ft	$ 866.01	$ 794.51	$ 798.99
Building Square Footage	4,320	3,200	7,520
MVS Building Costs	$ 3,741,182	$ 2,542,437	$ 6,008,376
Final MVS Cost Per Sq Ft	$ 866.01	$ 794.51	$ 798.99

Source: DI #2, Exh. 10 and DI #9, Exh. 19.

Commission staff calculated the estimated cost at **$525.38 per SF**, a difference that is $273.61 (about 34.6%) below the calculated MVS Benchmark.

Table 2: Comparison of Renovation Budget to Marshall Valuation Service Benchmark

	Phase 1	Phase 2	Total
Building	$ 1,890,967	$ 2,291,407	$ 4,182,374
Arch./Eng. Fees	$ 158,245	$ 191,755	$ 350,000
Permits	$ 1,809	$ 2,191	$ 4,000
Subtotal	$ 2,051,021	$ 2,485,353	$ 4,536,374
Adjustments			
Infection Prevention	$ 94,548	$ 114,570	$ 209,119
Premium for Constrained Site	$ 94,548	$ 114,570	$ 209,119
Premium for Minority Business Enterprise Requirement	$ 75,639	$ 91,656	$ 167,295
Total Adjustments	$ 264,735	$ 320,796	$ 585,533
Net Project Costs	$ 1,786,286	$ 2,164,557	$ 3,950,841
Project Cost for MVS Comp	$ 1,786,286	$ 2,164,557	$ 3,950,841
Square Footage	4,320	3,200	7,520
Cost Per Square Ft.	$ 413.49	$ 676.42	$ 525.38
Adj. MVS Cost/Square Foot	$ 866.01	$ 794.51	$ 798.99
Over(Under)	$ (452.52)	$ (118.09)	$ (273.61)
Over(Under) Costs	$ (1,954,896)	$ (377,880)	$ (2,057,535)

Source: DI #2, Exh. 10 and DI #9, Exh. 19.

Table 2 shows that Commission staff calculated the cost of renovating 7,520 SF at $3,950,841, which includes $585,533 of extraordinary costs that are excluded in determining the MVS benchmark value for this project.

As previously stated, the MVS methodology does not offer useful data that provides for the comparison of the cost of a proposed construction project to that of similar projects as part of a cost-effectiveness analysis for renovation projects. As observed in Table 2 above, the calculated MVS benchmark value ($798.99 per SF) exceeds UMMC's cost of $525.38 per SF to renovate 7,520 SF in the surgical suites located in the UMMC Children's Heart Program.

APPENDIX 6

PROJECT BUDGET

UMMC Hybrid OR Project Budget

Renovations	
Building	$4,182,374
Architect/Engineering Fees	$350,000
Permits (Building, Utilities, Etc.)	$4,000
SUBTOTAL Renovations	***$4,536,374***
Other Capital Costs	
Movable Equipment	$4,000,000
Contingency Allowance	$540,000
Gross interest during construction period	$0
Other (Owner Cost)	$220,000
SUBTOTAL Other Capital Costs	***$4,760,000***
TOTAL CURRENT CAPITAL COSTS	***$9,296,374***
Inflation Allowance	$223,626
TOTAL CAPITAL COSTS	***$9,520,000***
Financing Cost and Other Cash Requirements	
Loan Placement Fees	$0
CON Application Assistance	
Legal Fees	$35,000
Other	$0
SUBTOTAL Financing Costs and Other Cash Requirements	***$35,000***
Total Project Cost	***$9,555,000***

Source: DI #2, Table E

APPENDIX 7

HEALTH SERVICES COST REVIEW COMMISSION STAFF'S REVIEW AND OPINION

maryland
health services
cost review commission

MEMORANDUM

TO: Laura Hare, Program Manager, CON, MHCC

FROM: Katie Wunderlich, Executive Director, HSCRC
Jerry Schmith, Director, Revenue & Regulation Compliance, HSCRC

DATE: February 24, 2021

RE: University of Maryland Medical Center (UMMC)
Pediatric Cardiac Operating Room Suite Project
Docket No. 20-24-2445

****

This memo is in response to your request dated February 22, 2021. University of Maryland Medical Center (UMMC) has submitted a Certificate of Need (CON) application proposing to expand the capacity of its pediatric cardiac surgical and interventional service line by adding one special purpose hybrid operating room (OR) that will serve the University of Maryland Children's Hospital Pediatric Cardiac Program. You have requested that the staff of HSCRC review the financial projections provided in the CON application and subsequent filings, and advise MHCC on the general financial feasibility of the proposed project. MHCC staff believes that the utilization projections presented in the application are reasonable and has asked HSCRC staff to assume that UMMC will achieve the projected volumes.

BACKGROUND

As you have described it, located on the seventh floor of the North Building, the Children's Heart Program has an existing single special purpose hybrid OR that contains highly specialized equipment for heart surgeries and cardiac catheterization procedures addressing congenital heart issues. Phase one of the project will create space for the new hybrid OR by relocating support services within the existing OR suite and relocating two existing mixed-use general purpose ORs into the vacated support service space. Phase two of the project will involve constructing the proposed second hybrid OR in the footprint of the two relocated mixed-use general purpose ORs. Upon project completion, the pediatric cardiac OR suite will have three general purpose and two hybrid ORs.

THE PROJECT

The total capital cost of the project is estimated at $9.56 million including: approximately $4.55 million in renovations; $4 million in movable equipment; $540,000 in contingency allowance; $220,000 in owners' costs; $223,000 in inflation allowance; and $35,000 in legal fees. The applicant will fund this project with $3.0 million in philanthropy and $6.56 million in cash from operations.

HSCRC REVIEW, DISCUSSION, and OPINION

HSCRC staff has reviewed the following: 1) the CON application dated November 13, 2020; and 2) the subsequent Completeness Responses dated December 14, 2020.

Upon review of the statistical and financial information provided in the CON and subsequent completeness responses, it was noted that the project's projected P&L reflects the incurrence of $1.5M in incremental operating expenses (all of which was labor) with no incremental revenue to cover them. Therefore, this project yields a projected $1.5M operating loss per year. Additionally, UMMC does neither requests nor projects

rate relief in the CON. As per review of the audited financial statements, UMMC had an Operating Profit for FY 2020 of $92.6M; therefore, it is apparent that UMMC can absorb the projected loss without any material adverse impact upon its performance.

Consistent with the project budget, the funding sources for the project include $3M from philanthropy and $6.6M from available cash balances. There is no debt financing planned. As documented in the completeness responses, the applicant represents that it has fully collected the $3M in targeted gifts. As per review of the audited financial statements, UMMC had $19M in cash at June 30, 2020, while the University of Maryland Medical System consolidated had $962M in cash on that date. Therefore, it is apparent that UMMC has the needed resources to finance the project.

Based upon staff's review of the information presented, the HSCRC believes that the special purpose hybrid operating room project appears to be financially feasible.

Cc: Kevin McDonald, Chief, CON, MHCC
Bill Chan, Program Manager, CON, MHCC

APPENDIX 8

UMMC'S ACTION PLANS FOR QUALITY MEASURES THAT RATED BELOW AVERAGE

UMMC Action Plans for Below Average Quality Measures

Measure	Action Plan
How long patients spent in the emergency department before leaving their hospital room	The applicant developed a multidisciplinary performance improvement plan, including Emergency Medicine, Patient Access, Inpatient Meidcine, Nursing, and EVS, to address all of these measures and increase flow between the Emergency Department and medicine/inpatient care floors. This plan includes eliminating rework stepts, automativng processes, and promoting transparency in the process. The plan also focuses on increasing communication between the ED and medicine floors to streamline admissions and transfers.
How long patients spent in the emergency department after the doctor decided the patient would stay in the hospital before leaving for their hospital room	
How long patients spent in the emergency department before being sent home	
Patients who left the emergency department without being seen	
Patients in the hospital who got the flu vaccine if they were likely to get flu	The applicant states that it does not track compliance as this is no longer a core measure. It will, however, maintain a patient flue vaccination program. UMMC developed a nurse driven program, where nurses are approved to conduct flue vaccine assessments and administration. The applicant also promoted compliance by enhancing the EHR data input system to increase visibility of the need for the vaccine on the patient level.
Patients who came to the hospital for a scan of their brain and also got a scan of their sinuses	Per CMS 2021 Hospital Outpatient Quality Reporting Program, this measure is no longer tracked. However, UMMC us of the maxiollofacial (brain and sinus) CT is limited to those situations in which both studies are ordered by the referring physician. It is often used in cases where trauma has occurred and imaging of the brain and facial bones is necessary.
Returning to the hospital for any unplanned reason within 30 days after being discharged	The applicant developed a mulitdiciplinary readmission prevention initiative, which has been applied across all of its services and departments to improve care transitions. The initiative includes focused intervention before hospitalization, during readmission, before and after discharge for patients previously readmitted and spans the continuum of care.
Death rate for stoke patients	The applicant is currently sponsoring a task force, lead by the Chairperson of Neurology, to perform a root cause analysis for the

	reported mortaility rates associated with this measure so that the program can alleviate this root cause and course correct. Also, each death is reviewed in case conference and morbidity and mortality rounds.
How often patients in the hospital had to use a breathing machine after surgery because they could not breath on their own	Each case identified with measure is shared with the appropriate medical/surgical service for case review and/or practice change in order to prepare for similar scenarios in the future.
How often patients in the hospital get a blood clot in the lun or leg vein after surgery	Each case identified with measure is shared with the appropriate medical/surgical service for case review and/or practice change in order to prepare for similar scenarios in the future.

(DI #2, Exh. 9).