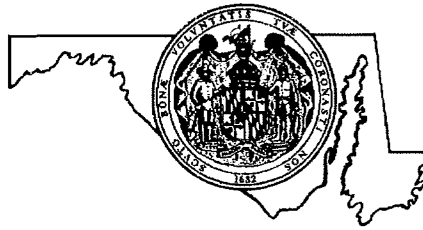
Robert E. Moffit
CHAIR

STATE OF MARYLAND



Ben Steffen
EXECUTIVE DIRECTOR

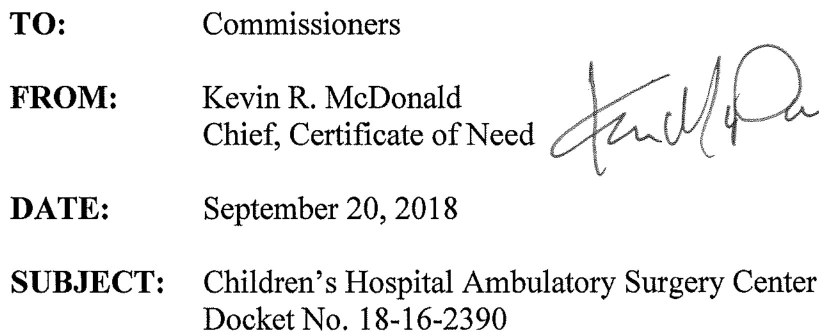
MARYLAND HEALTH CARE COMMISSION

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

MEMORANDUM

TO: Commissioners

FROM: Kevin R. McDonald
Chief, Certificate of Need



DATE: September 20, 2018

SUBJECT: Children's Hospital Ambulatory Surgery Center
Docket No. 18-16-2390

Enclosed is the staff report and recommendation regarding a Certificate of Need ("CON") application filed by Children's Hospital, a subsidiary of Children's National Medical Center, Inc., a network of pediatric care providers that includes the flagship hospital campus, six health centers in the District of Columbia and seven regional outpatient centers, including five in Maryland.

Children's Hospital plans to develop a new regional outpatient center Children's National of Prince George's County in Glenarden, MD, located within a newly-constructed multi-use commercial and residential property at 2900 North Campus Way. It will include an ambulatory surgical facility ("ASF") with two operating rooms.

Staff recommends that the Commission APPROVE the project based on staff's conclusion that the proposed project complies with the applicable standards in COMAR 10.24.11, the State Health Plan for General Surgical Services, and the CON review criteria at COMAR 10.24.01.08. Our recommendation includes two conditions:

1. The ambulatory surgical facility at Children's National of Prince George's County shall maintain compliance with the provisions of COMAR 10.24.16.08E(1)-(4) regarding charity care; and

2. The ambulatory surgical facility at Children's National of Prince George's County shall provide an amount of charity care equivalent to 0.56% of its operating expenses.

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IN THE MATTER OF	*	BEFORE THE
	*	
CHILDREN'S HOSPITAL	*	MARYLAND HEALTH
	*	
Docket No. 18-16-2413	*	CARE COMMISSION
	*	

* *

Staff Report and Recommendation

September 20, 2018

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I. INTRODUCTION

THE APPLICANT

Children's Hospital ("CH") is a subsidiary of Children's National Medical Center, Inc. ("CNMC"), a network of pediatric care providers that includes the flagship hospital campus and six health centers in the District of Columbia, Children's Pediatrics & Associates with more than 50 providers throughout the District of Columbia and Maryland, and seven regional outpatient centers ("ROCs"), including five in Maryland, located in Annapolis, Laurel, Rockville, Upper Marlboro, and Frederick. (DI #2, pp. 5-8).

Children's Hospital plans to develop Children's National of Prince George's County, a new regional outpatient center, in Glenarden (Prince George's County). The proposed ROC will feature specialists in otolaryngology, general surgery, gastroenterology, ophthalmology, plastic surgery, urology, and orthopedics. (*Id.*, pp. 4, 10). The ROC will be located within a newly-constructed planned multi-use commercial and residential property at 2900 North Campus Way in Glenarden. (*Id.*, p. 1 & 28). The site will be accessible by bus, with connections to Metro rail service. (DI #9, p. 22). This new ROC will consolidate the services currently located at the Laurel and Upper Marlboro ROCs. (DI #2, pp. 4 & 10).

THE PROJECT

The applicant proposes the establishment of an ambulatory surgical facility ("ASF") with two operating rooms at the new Glenarden ROC. (DI #2, p. 4). Neither of the existing ROCs in Laurel or Upper Marlboro that are being replaced by this new regional center currently provides surgical services. (DI #20, p. 86).

The proposed ASF will consist of 10,550 square feet of space on the third floor of the center and is estimated to cost approximately $10.4 million, with $4.3 million for construction, $5.7 million for moveable equipment, $326,000 for contingencies, and $57,000 for CON application assistance. CH anticipates funding the project with cash, and expects to open for service within 14 months of capital obligation and to reach full capacity within 36 months. (DI #2, p. 14 & Exh. 6).

STAFF RECOMMENDATION

Staff recommends that the Commission issue a CON for the proposed ambulatory surgical facility based on staff's 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, with the following conditions:

1. The ambulatory surgical facility at Children's National of Prince George's County shall maintain compliance with the provisions of COMAR 10.24.16.08E(1)-(4) regarding charity care; and

2. The ambulatory surgical facility at Children's National of Prince George's County shall provide an amount of charity care equivalent to 0.56% of its operating expenses.

Children's Hospital has demonstrated that the project is needed. Staff concludes that CH's current surgical case volume for area pediatric patients, which will be augmented by projected growth in demand for pediatric ambulatory surgical services in the service area, justifies the proposed two operating rooms. The project is viable, and will be a cost-effective alternative for meeting the project's objectives of increasing CNMC's outpatient surgical capacity in order to increase availability of outpatient pediatric surgery to Maryland residents. The project will have a positive impact on patient access to services offered by the CNMC network, on the cost to the health care delivery system, and will not have a negative impact on other providers.

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 a local governmental body.

D. Community Support

Twelve letters of support for the project were submitted with the CON application by: three elected officials, Maryland Delegate Barnes (District 25), Maryland Senator Joanne Benson (District 24), and Mayor Eugene Grant of Seat Pleasant; three parents whose children received services from the Children's network and who stated that the new ROC location will be more convenient for them; four staff members at Children's National Medical Center, including the program administrator of the Parent Navigator Program; a professor of Pediatrics and Surgery at CNMC; CNMC's Chief of the Division of Orthopaedic Surgery and Sports Medicine; and a professor of Otolaryngology and Pediatrics at CNMC; Colenthia Malloy, CEO of Greater Baden Medical Services, a Federally Qualified Health Center with seven locations in Southern Maryland; and Kevin Maxwell, then-CEO of Prince George's County Public Schools. (DI #2, Exh. 21).

III. STAFF REVIEW AND ANALYSIS

The Commission reviews CON applications under six criteria found at COMAR 10.24.01.08G(3). The first of these considerations is the relevant State Health Plan standards, policies, and criteria.

A. The 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 for Facilities and Services ("SHP") chapter in this review is the General Surgical Services chapter, COMAR 10.24.11 ("Surgical Services Chapter").

.05 STANDARDS

A. GENERAL STANDARDS. The following general standards encompass Commission expectations for the delivery of surgical services by all health care facilities in Maryland, as defined in Health General §19-114(d). Each applicant that seeks a Certificate of Need for a project or an exemption from Certificate of Need review 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.

Information regarding charges for surgical services shall be available to the public. A hospital or an ambulatory surgical facility 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.

Children's Hospital states that it will provide information to the public concerning estimated charges for specific pediatric outpatient surgical services, upon inquiry, as required by applicable regulations or law. The applicant states that its staff will work with each patient individually to determine the estimated cost for services, including copays and deductibles, based on the patient's unique coverage. (DI #9, p. 73).

Staff concludes that CH satisfies this standard.

(2) Charity Care Policy.

(a) ***Each hospital and ambulatory surgical facility shall have a written policy for the provision of charity care that ensures access to services regardless of an individual's ability to pay and shall provide ambulatory surgical services on a charitable basis to qualified indigent persons consistent with this policy. The policy shall have the following provisions:***

The charity care policy that CH submitted with its application applies to all of the CNMC network subsidiaries. Upon review, staff determined that the policy as written did not comport with certain sections of this standard. Ongoing discussions between MHCC staff and the applicant and the applicant's revisions of the policy resulted in an approvable policy, as reflected in the discussion of each subpart of the standard.

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

With regard to the two-day determination of probable eligibility required by Subparagraph (2)(a)(i), CNMC's revised policy now ensures that a determination of probable eligibility will be made within two days based on "preliminary information provided by the patient, to include name, address, and family size and income," and that a final decision will be contingent upon verifying this information. (DI #29A, p. 3). CH also provides each uninsured patient with a one-page "plain language summary" of the financial assistance policy at registration. (DI #29B).

Staff notes that eligibility for financial assistance at CNMC facilities is restricted to "patients that have resided in our service area[1] for at least six months," although the policy states that it "may cover patients that do not reside in our service area when the hospital provides medical service to treat and stabilize the medical condition of the patient before discharge." (DI #29A, p. 3). This restriction of eligibility for financial assistance based on residency in an applicant's service area is not a provision that MHCC staff has seen before and, as discussed, is totally dependent upon the nature of national children's hospitals, such as CNMC. Staff asked the applicant to explain the rationale and justification for this provision.

CH responded that

> the financial assistance policies of the vast majority of the top children's hospitals in the United States include a geographical limitation on eligibility for financial assistance, [and that] eliminating this eligibility requirement could rapidly attract patients requiring financial assistance from across the country and the world. (DI #20, p. 87).

To document that statement, CH provided copies of the charity care policies of a sampling of the financial assistance policies for the top ten children's hospitals in the United States,[2] as determined by U.S. News & World Report, pointing out that "eight out of the top ten children's hospitals in the United States ... include a geographical limitation on eligibility for financial assistance and apply a qualifying test of residence within the specified area." (DI #20, pp. 87, 88).[3] CH summarized – and staff confirmed – the residency requirements referenced in these facilities' financial assistance policies, shown in Table III-1 immediately below.

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[1] The policy defines the service area as all counties in Maryland, Washington, DC, Alexandria, Virginia, and the Virginia counties of Arlington, Fairfax, Fauquier, Loudon, Prince William, and Stafford.

[2] CH notes that the FAP applies not just to the subject of this application, but to all Children's facilities, services, programs, and settings, including Children's Hospital itself. The applicant also notes that "Children's was just named to the list of top 5 pediatric hospitals in the country by US News & World Report, and its NICU was named #1 for the 2nd year in a row, along with 7 other specialties ranked in the top ten."

[3] Referencing U.S. News & World Report's 2017-2018 report and its 2018-2019 report.

Table III-1: Residency Requirements for Financial Assistance at a Select Sampling of Children's' Hospitals

2018-2019 U.S. News & World Report Best Children's Hospitals Honor Roll			
Rank	Hospital	Location	Residency Requirement
1	Boston Children's Hospital	Boston, MA	Commonwealth of Massachusetts
2	Cinncinati Children's Hospital Medical Center	Cinncinati, OH	State of Ohio or Primary Service Area: 4 OH counties, 3 KY counties, 1 IN county
3	Children's Hospital of Philadelphia	Philadelphia, PA	Primary Service Area: 9 PA counties, 13 NJ counties, 1 DE county
4	Texas Children's Hospital	Houston, TX	Primary Service Area: 8 TX counties
5	Children's National Medical Center	Washington, DC	Primary Service Area: District of Columbia, all Maryland counties, 6 VA counties
6	Children's Hospital Los Angeles	Los Angeles, CA	None
7	Nationwide Children's Hospital	Columbus, OH	State of Ohio
8	Johns Hopkins Children's Center	Baltimore, MD	None
9 (2017)[1]	Children's Hospital of Pittsburgh of UPMC	Pittsburgh, PA	Primary Service Area: All counties contiguous to a UPMC facility
9 (2018)	Children's Hospital Colorado	Aurora, CO	State of Colorado
10	Ann and Robert H. Lurie Children's Hospital of Chicago	Chicago, IL	State of Illinois

[1]Children's Hospital of Pittsburgh of UPMC was replaced by Children's Hospital Colorado in the 2018-2019 rankings, but remains a top ten children's hospital for numerous specialties.

Further explaining its rationale and need for a residency restriction, CH states that

> [a]s its national prominence increases with these most recent rankings, Children's expects to experience additional influx of patients, including those requiring financial assistance, from across the country and around the world. Absent the current geographic restriction included in the FAP, such an influx could constrain resources utilized to care for patients from the communities Children's exists to serve."
> (DI #20, p. 87).

(ii) Notice of Charity Care Policy. Public notice and information regarding the facility's charity care policy shall be disseminated, on an annual basis, through methods designed to best reach the facility's service area population and in a format understandable by the service area population. Notices regarding the surgical facility's charity care policy shall be posted in the registration area and business office of the facility. Prior to a patient's arrival for surgery, facilities should address any financial concerns of patients, and individual notice regarding the facility's charity care policy shall be provided.

With regard to Subparagraph 2(a)(ii)'s requirement for Notice of Charity Care Policy, Children's Hospital states that: its financial assistance policy is a public document and is available to all patients upon request; notices regarding the availability of financial assistance are posted across Children's network of campuses and facilities; it is made available to social service agencies and other entities that come into contact with people who may need financial assistance; CH publishes its policy in local newspapers on a regular basis; and, perhaps most importantly, it is posted on Children's website. (DI #20, p. 87). In addition, as previously noted, the applicant has a "plain language" version of its financial assistance policy. (DI #29B). CNMC has also historically shared its financial assistance policies via e-mail with federally qualified health centers that operate in the District of Columbia and Prince George's County including Unity Health Care, Mary's Center, and Community of Hope, as well as Bread for the City, a comprehensive social services

organization that supports low-income residents in the region. The applicant plans to identify additional social services agencies with which it will share its financial assistance plan once the new ASF is completed. (DI #25, p. 105). This will include such health centers as Greater Baden Medical Services, which provided a letter of support. (DI #2, Exh. 21; DI #25, p. 105).

The applicant provided a copy of its notice of the availability of financial assistance to be included in patient statements and photographs of existing signage in the registration areas, emergency room, and pulmonary clinic of CNMC, which notify patients and families of the availability of financial assistance, in both English and Spanish. (DI #20, Exh.. 32, 33). The policy states that "prior to their arrival for surgery, CNMC will address any financial concerns patients may have, and individual notice regarding this FAP [financial assistance policy] shall be provided to the patient ...." (*Id.*, Exh. 30, p. 5).

(iii) Criteria for Eligibility. Hospitals shall comply with applicable State statutes and HSCRC regulations regarding financial assistance policies and charity care eligibility. ASFs, at a minimum, must include the following eligibility criteria in charity care policies. 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. At a minimum, 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. 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 ASFs described in these regulations.

With regard to the Subparagraph (2)(a)(iii) regarding Criteria for Eligibility, CNMC's policy is to provide medically necessary services free of charge to patients whose family income is at or below 400% of the federal poverty guidelines, rather than instituting a sliding scale of fees for services. Commission Staff notes that this is a more generous policy than required under the Charity Care standard, which requires that services be provided free of charge for persons with family income below 100 percent of the federal poverty guideline and a sliding scale of discounts for family income bands between 100% and 200% of federal poverty level. (DI #20, Exh. 30, p 4).

(b) A hospital with a level of charity care ... that falls within the bottom quartile... shall demonstrate that its level of charity care is appropriate to the needs of its service area population.

This standard is not applicable to this review. It addresses hospitals seeking to add OR capacity, while this application proposes the establishment of an ambulatory surgery facility.

(c) A proposal to establish or expand an ASF 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 ASFs 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; and

The applicant made a commitment to provide at least the average amount of charity care provision by ASFs for the most recent year available; that target is 0.56%.[4] The applicant's projected charity care exceeds that benchmark, as shown in Table III-2 below. (DI#2, p. 56).

Table III-2: Projection of Charity Care as a Percentage of Total Operating Expenses Proposed ASF, Children's National of Prince George's County Projected for CY 2020 through CY 2023 (Projected Years 1-4 of Operation)

	2020	2021	2022	2023
Charity Care	$98,561	$112,473	$205,476	$212,141
Total Operating Expense	$4,801,823	$5,577,880	$7,779,617	$7,965,416
% Charity Care	2.05%	2.02%	2.64%	2.66%

Source: DI #2, pp. 56; Commission Staff analysis of data presented by the applicant.

The applicant's track record supports the credibility of its commitment. An ASF in Montgomery County operated by the CNMC network provided charity care equivalent to 4.6% of its operating expenses in CY 2016, far exceeding the 0.56% ASF average.

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

The applicant has a specific plan for achieving its charitable care commitment. That plan includes notifying the public concerning the availability of charity care by posting notices prominently within the new outpatient center and ASF, continuing to post a summary of the charity care policy on websites, in brochures, and in the community served by the outpatient center and ASF, and publishing annual notices in a newspaper of record in Prince George's County. As mentioned earlier, each uninsured patient is given a one-page "plain language summary" of the financial assistance policy at registration. Finally, the applicant plans to remind physicians about the policy via an annual email from the Chief Medical Officer and remind staff about financial assistance services and the charity care policy annually via meetings and email. Updates will be communicated in a similar manner. (DI #25, p. 106).

(iii) If an existing ASF has not met the expected level of charity care for the two most recent years reported to MHCC, the applicant shall demonstrate that the historic level of charity care was appropriate to the needs of the service area population.

This subparagaph does not apply, since the proposed project is not an existing ASF. Furthermore, CH's ASF in Montgomery County exceeds the historic level of charity care provision by Maryland ASFs.

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[4] Preliminary unaudited data from MHCC's Freestanding Ambulatory Surgery Center Survey indicates that in CY 2016 ambulatory surgery centers provided charity care totaling 0.56% as a percentage of total operating expenses.

Staff concludes that the applicant has met the requirements of all components of the charity care standard. Staff recommends that any approval of this project be issued with the following conditions:

1. The ambulatory surgical facility at Children's National of Prince George's County shall maintain compliance with the provisions of COMAR 10.24.16.08E(1)-(4) regarding charity care; and

2. The ambulatory surgical facility at Children's National of Prince George's County shall provide an amount of charity care equivalent to 0.56% of its operating expenses.

Standards .05A(3) Quality of Care, .05A(4) Transfer Agreements, and .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(3) Quality of Care
.05A(4) Transfer and Referral Agreements
.05B(4) Design Requirements, and
.05B(5) Support Services.

In responding to these standards, the applicant:

- Provided evidence that the proposed ASF will meet the requirements for licensure in Maryland under COMAR 10.05.05 and stated that it will obtain accreditation from the Joint Commission within two years of initiating services. (DI #2, pp. 26-27).

- Submitted a copy of the Transfer Agreement between the Prince George's County outpatient center and CNMC in the District of Columbia, which specifies the responsibilities of each party in ensuring the appropriate and safe transfer of patients between the facilities. It is the outpatient facility's responsibility to provide for appropriate and safe transfer of the patient to the hospital, to notify the hospital of the estimated time of arrival of the patient, to send medical information to continue the patient's treatment without interruption, and send essential identifying information on referral forms with each patient. (DI #9, Exh. 23).

- Submitted a letter from its principal architect, Jeffrey Brand at Perkins-Eastman, stating that the construction is designed in compliance with the 2014 FGI Guidelines for Design and Construction of Hospitals and Outpatient Facilities,

Chapter 3.7 Specific Requirements for Outpatient Surgical Facilities. (DI #2, Exh. 17).

- Stated that the proposed ASF will be located in an outpatient center that includes phlebotomy, laboratory, transfusion services, and an imaging center. Advanced laboratory and pathology services will be available via courier to the main CNMC campus. (DI #2, p. 42).

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 primary service area for the proposed ASF includes zip code areas in Prince George's, Charles, Anne Arundel, St. Mary's, and Calvert Counties in Maryland. The secondary service area includes Montgomery County, Howard County, and District of Columbia zip code areas. (DI #2, pp. 30-31, Exh. 15).

Children's Hospital identified the service area for the proposed ASF consistent with the 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 demonstrate the need for the number of operating rooms proposed for the facility. This need demonstration shall utilize the operating room capacity assumptions and other guidance included in Regulation .06 of this Chapter. This needs assessment shall demonstrate 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.

(a) An applicant proposing the establishment or replacement of a hospital shall submit a needs assessment that includes the following….

This subpart is not applicable.

(b) 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.

To meet this standard, an applicant must submit a needs assessment that accounts for historic trends in the use of surgical facilities for outpatient surgical procedures in the service area, operating room time required for surgical case projections at the proposed ASF, and documentation of the current surgical caseload of each physician likely to perform surgery at the ASF.

CH projects that most of the surgical case volume at the proposed center will represent a redistribution of cases within the CNMC network, i.e, cases historically handled at Children's National Medical Center in Washington, D.C. that will be moved to the proposed facility, growth in demand for outpatient surgery coincident with growth of the pediatric population in the area, and a shift in pediatric surgery market share from other providers.

The applicant projects that, during the first two years of operation, the utilization at the proposed ASF will be volume that originates from areas that are geographically closer to the proposed ASF but that would otherwise be handled at CNMC. At full utilization, CH projects that the surgical cases migrating to the proposed ASF will ultimately account for more than 80% of cases. The applicant identifies growth in demand, generated from population growth and success in shifting market share from other providers as accounting for the remainder.[5] (DI #27, p. 1).

The applicant reports that CNMC experienced 6% growth in total same-day surgical cases between FY 2016 and FY 2017, as displayed in Table III-3 below.

[5] CH utilized forecasts for pediatric ambulatory surgery demand created by Truven Health Analytics, Inc., which projected demand for pediatric ambulatory surgery procedures to increase by 7% over the next five years and 13% over the next ten years. This forecast led to the applicant's projection that pediatric surgical cases originating from within the the new ASF's primary service area counties will increase by 720 cases by 2027. (DI #2, pp. 35-36; DI #9, p. 79).

Table III-3: CNMC Ambulatory Surgery Cases by Patient Jurisdiction of Origin, FY 2016 and FY 2017, and Projected Case Volume Migration from CNMC To the Proposed Ambulatory Surgical Facility

Jurisdictions	FY 2016	FY 2017	Projected Migration, based on FY 2017 Utilization	
	Cases	Cases	Percent	Cases
Primary Service Area				
Prince George's	2,249	2,334	50%	1,167
Charles	428	425	50%	213
Anne Arundel	184	208	75%	156
St. Mary's	195	212	50%	106
Calvert	157	162	50%	81
Total PSA	**3,213**	**3,341**		**1,723**
% of Total	*34.6%*	*33.9%*		
Secondary Service Area				
District of Columbia	1,994	2,194	10%	219
Montgomery	1,536	1,695	5%	85
Howard	85	88	25%	22
Total SSA	**3,615**	**3,977**	**--**	**326**
% of Total	*38.9%*	*40.4%*		
Other Selected Maryland				
Frederick	216	221	0%	-
Washington	95	128	0%	-
Eastern Shore	86	100	75%	75
Baltimore County/City	46	49	5%	2
Other	30	37	0%	-
Total Other MD	**473**	**535**	**-**	**77**
Other States				
Virginia	1,802	1,770	0%	-
West Virginia	69	79	0%	-
Pennsylvania	25	30	0%	-
Other	92	109	0%	-
Total Other States	**1,988**	**1,988**	**-**	**-**
Total Maryland	**5,307**	**5,659**	**-**	**-**
% of Total	*57.1%*	*57.5%*		
Total Same-Day Surgical Cases	**9,289**	**9,841**	**-**	**2,126**

Source: Data from Children's National Medical Center (DI #25, p. 109,

Fifty-eight percent (58%) of the cases that took place at CNMC's main campus in the District of Columbia were performed on patients from Maryland, with the bulk (40%) coming

from jurisdictions in the proposed project's primary and secondary service areas. (DI #9, p. 69; DI #25, p. 107).

CH projects that 50% to 75% of these cases originating from the primary service area will migrate from CNMC's main campus to the proposed ASF, as will 5% to 25% (varying by county) of the cases originating from the secondary service area. It projects some level of migration of CNMC's hospital cases coming from the Eastern Shore and Baltimore areas. Based on these assumed migration rates, the applicant estimated as many as 2,126 cases of its FY 2017 utilization would have used the proposed ASF – had it been available – rather than the hospital, because of its geographic proximity. (DI #25, p. 109).

Current Surgical Caseload of Each Physician Likely to Perform Surgery at The Proposed Facility

Table III-4 below shows the applicant's projections by specialty, and the current and projected surgical caseload of surgeons who are expected to perform surgery at the proposed ASF through Year 3: about 1,291 cases in Year 1, followed by 10% annual growth in Year 2, and around 79% annual growth in Year 3.

Table III-4: TJSC Historical and Projected Utilization, CY 2012-CY 2020

Physician	Actual most recent utilization				Projections at Proposed ASF					
	FY 2016		FY 2017		Year 1		Year 2		Year 3	
	Cases	Minutes	Cases	Minutes	Cases	Minutes	Cases	Minutes	Cases	Minutes
Espinel	NA	NA	533	20,029	121	4,547	128	4,810	140	5,261
Mudd	501	23,547	592	29,090	107	5,136	112	5,076	130	6,240
Pena	488	20,556	564	23,821	119	5,026	123	5,166	125	5,250
Preciado	416	19,865	479	25,387	73	3,869	73	5,329	125	6,625
Petrosyan	649	35,695	672	47,712	334	21,710	344	22,360	385	25,025
Matta	NA	NA	83	3,320	84	3,360	86	3,440	172	8,428
Jacobs/ Perez-Albuerne	35	3,360	50	4,500	25	2,250	26	2,340	52	4,680
Bazemore	97	7,828	63	5,696	38	3,116	39	3,159	40	3,240
deBeaufort	46	3,548	75	6,349	39	3,198	40	3,360	42	3,528
Niu	NA	NA	143	19,747	30	3,750	31	4,278	32	4,000
Rogers	159	10,702	168	12,629	84	6,132	100	7,300	120	8,760
Kalloo	213	17,713	156	15,288	117	9,711	122	10,126	137	11,371
Evaas	166	4,131	205	4,752	58	1,334	60	1,380	139	3,197
Other Urology					62	5,146	62	5,146	128	10,624
Other ENT							85	4,505	280	14,840
Other General									303	19,695
Other Orthopedics									50	6,250
Other Community Physicians									155	16,895
Total	**2,770**	**146,945**	**3,783**	**218,320**	**1,291**	**78,285**	**1,431**	**87,775**	**2,555**	**163,909**

Source: DI #20, Exh. 35.

Projected Operating Room Time at the Proposed ASF

Based on its case volume projections, the applicant provided the estimated operating room ("OR") demand shown in Table III-5 below.

Table III-5: Projected Utilization at Proposed ASF, Years 1 through 3

		OR Cases	Operating Room and OR Preparation Time			ORs Needed at Optimal Capacity
			Surgical Procedure Time (minutes)	Turnaround Time (25 minutes per case)	Total OR Time	
Projected	Year 1	1,291	78,285	32,275	110,560 minutes *(1,843 hours)*	**1.13**
	Year 2	1,431	87,775	35,775	123,550 minutes *(2,059 hours)*	**1.26**
	Year 3	2,555	163,909	63,875	227,784 *(3,796 hours)*	**2.33**

Source: DI #20, Exh. 35; Additional analysis of applicant's data by Commission Staff

Based on this projected utilization, CH projected that the proposed ASF will have demand for two rooms operating at more than optimal capacity[6] in Year 3. Staff concludes that because the largest portion of the applicant's projections are based on the migration of existing cases from CNMC's main campus in the District of Columbia to the proposed ASF, as well as forecasted new demand for ambulatory surgical services in the primary service area, the proposal supports the need for two ORs at the Regional Outpatient Center in Prince George's County. Thus, the proposed project is consistent with this standard.

(3) ***Need – Minimum Utilization for Expansion of An Existing Facility.***

This standard is not applicable. The proposed project involves establishment of a new ambulatory surgical facility.

(6) ***Patient Safety.***

The design of 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.

The applicant states that patient safety plays a critical role in every decision made by CH leadership. For the proposed project, the safety-related objectives are: maintenance of effective infection prevention and control barriers; reduction of opportunities for medical error; and minimization of staff response time in the event of an emergency. CH notes that its consideration of design of the facility also focused on maximizing privacy and comfort for patients and families. (DI #2, p. 43).

[6] COMAR 10.24.11.07A(1)(b) defines optimal capacity as 80 percent of full capacity (2,040 hours per year per OR). Thus, in Year 3, CH's projected OR use is within MHCC's full capacity assumption for a dedicated outpatient OR.

The applicant states that the proposed project follows the 2014 FGI Guidelines for Design of Construction of Hospitals and Outpatient Facilities, and cited a number of specific design features, including: use of antimicrobial surfaces to limit acquired infections; prep and recovery rooms that are designed as private rooms with glass intensive care unit-style sliding doors with a break-away feature to enhance privacy, reduce public access, and allow quick removal of the patient in the event of an emergency; private sinks in each room to improve infection control by providing caregivers and patient family members direct access to handwashing facilities; acoustic control with gypsum board on interior walls that runs to the bottom of the slab above to limit the transfer of noise between patient rooms to enhance privacy and communication among staff; and standardized operating rooms, equipment, and supply locations to improve staff efficiency during surgical procedures so as to lessen the opportunity for errors. *(Id.*, pp. 44-45). A copy of the project floor plan drawing is included in Appendix 3.

Staff concludes that the applicant considered patient safety in its design of the proposed ASF, and meets this standard.

(7) ***Construction Costs.***

The cost of constructing surgical facilities shall be reasonable and consistent with current industry cost experience.

(a) Hospital projects.

Subpart (a) does not apply because this is not a hospital project.

(b) Ambulatory Surgical Facilities.

(i) The projected cost per square foot of an ambulatory surgical facility construction or renovation project 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.

(ii) If the projected cost per square foot exceeds the Marshall Valuation Service® benchmark cost by 15% 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.

Paragraph (b) of this standard requires a comparison of the project's estimated construction cost with an index cost derived from the Marshall Valuation Service ("MVS") guide. To complete this comparison, an MVS benchmark cost is developed for new construction based on the relevant construction characteristics of the proposed project. The MVS cost data include the base cost-per-square-foot for new construction by type and quality of construction for a wide

variety of building uses including outpatient surgical centers. 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.[7]

Both CH and MHCC staff performed independent analyses comparing the applicant's estimated project cost to the MVS benchmark calculated for the proposed project. (See Appendix 4). In this project CH proposed the construction of 10,700 square feet ("SF") of new building space for the ASF on the third floor. Based on a total project cost of $3,379,630, the applicant and MHCC staff each calculated an estimated cost for the contruction of the ASF at $315.85 per SF.

The applicant and MHCC staff arrived at slightly differing MVS benchmark values. CH calculated an estimated benchmark cost of $309.28, whereas MHCC staff calculated a value of $304.95 per SF. While staff utilized the MVS methodology to arrive at its benchmark value, CH utilized the Corelogic Swift Estimator Commercial Estimator software package to calculate the base cost for good quality Class A construction of an outpatient surgical center. While the methodologies used by both included subtracting the cost per square foot related to the shell of the medical office building ("MOB") from the ambulatory surgery center, the difference in the values is primarily due to how the initial net base costs (located in Appendix 4, Table B) were calculated. The applicant arrived at a net base cost per SF of $441.36 for constructing the ASF and $264.16 for fitting out the MOB space.[8] Staff's values were lower, at $379.00 for the ASF and $235.00 for the MOB. In addition, there were differences in the values used for the perimeter, story-height, current cost, and locality multipliers used by CH and staff.

Using the proposed construction cost of $315.85 per sq. ft., CH estimated its project cost to be $6.57 per SF (about 2.1%) higher than the calculated MVS benchmark, while MHCC staff's analysis found the estimated project cost to be $10.90 per SF (about 3.6%) above the MVS benchmark. The difference between CH's and staff's MVS values was $4.33 per SF, less than two percent. In either scenario, the projected cost of constructing the ASF did not exceed the calculated MVS benchmark value by 15%. Thus, the project complies with the standard.

(8) <u>Financial Feasibility.</u>

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[7] Marshall Valuation Service Guidelines, Section 1, p. 3 (January 2016).

[8] In evaluating the cost of constructing the ambulatory surgery facility, both the applicant and MHCC adjusted their respective benchmarks for the construction costs of a freestanding ambulatory surgery center to account for the fact that the proposed project involves the finishing of building space in a medical office building ("MOB") and not the construction of an entire new facility. Both approached the project as the completion of shell space within a MOB rather than as the construction of a standalone freestanding ambulatory surgery center.

A surgical facility project shall be financially feasible. Financial projects 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 projects.

(a) An applicant shall document that:

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

The applicant's utilization projections are based in large part on historic utilization trends, consisting primarily of the migration from CNMC, based on patients' counties of origin, as well as a projection to capture forecasted surgical service volume based on demographic changes, and market shifts. See discussion of COMAR 10.24.11.05(2), the Need standard, *supra*, pp. 9-13.

(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;

The applicant based its estimates of revenue on the previously discussed utilization projections. The level of reimbursement rates, bad debt, and contractual allowances are based on CH's experience at the CNMC network's existing ASF in Montgomery County.

(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 facility 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 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.

Staffing expense figures correlate with staffing volume projections. The applicant projects an excess of revenues over expenses by Year 3, followed by continued profitable operation, as shown in Table III-6. (DI #2, p. 27).

Table III-6: Children's National of Prince George's County Ambulatory Surgery Revenue, Expenses, and Income Projections, CY 2020 through CY 2023

CY	2020	2021	2022	2023
Cases	1,291	1,430	2,555	2,579
Net Revenue	$4,023,139	$4,591,005	$8,390,120	$8,665,183
Expenses	$4,801,823	$5,577,880	$7,779,617	$7,965,416
Net Income	$(778,684)	$(986,875)	$610,503	$699,767

Source: DI #2, pp. 51, 56.

Staff concludes that the applicant's utilization and financial projections are based on reasonable assumptions and that the application complies with this standard.

(9) Preference in Comparative Reviews.

This is not a comparative review, so this standard is not applicable.

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.

This criterion directs the Commission to consider the "applicable need analysis in the State Health Plan," which, in this instance, is found in the Surgical Services Chapter at COMAR 10.24.11.05B(2), Need – Minimum Utilization for Establishment of a New … Facility. As previously discussed (and supported by the data provided in Tables III-3 and III-4), the proposed ASF satisfies the Chapter's need standard. As noted, staff concludes that CH has addressed the need for two ORs based on its volume projections, which indicate that two ORs are likely to be used beyond optimal capacity within three years of the project's initiation.

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 ….

Children's Hospital states that the proposed project addresses the following goals:

- Create access to specialized surgical services for residents of eastern and southern portions of central Maryland, in general, and Prince George's County, in particular;
- Provide state-of-the-art facilities to accommodate current patient need and plan for future demand;
- Treat patients in the highest quality and most cost-effective setting; and
- Create additional capacity at Children's main campus to accommodate more complex patients and anticipated growth.

(DI #2, p. 52).

Children's Hospital states that it considered the following alternatives to the proposed project and also provided its rationale for choosing the proposed project.

- Building a freestanding ambulatory surgery center at another location would have been financially feasible. However, locating the ASF in the same location as other services in the new ROC provides more convenience and continuity of care for families and physicians.
- Building the new ROC at another location was considered. However, based on a comparative review of options, the applicant chose the Glenarden location due to more favorable and cost-effective building design and lease options.
- Expanding one of the existing ROC locations to include the ORs would not have been possible, as neither has available space. (DI #2, p. 53).

Although the applicant did not provide estimated costs for each of the alternatives listed, staff concludes that the choice of collocating a 2-OR ASF with an outpatient center is a cost-effective choice for meeting the project's goals of improving patient access and expanding surgical capacity, compared to the alternatives. Staff recommends that the Commission find the establishment of a 2-OR ASF at the proposed location to be the most cost-effective alternative for increasing OR capacity in order to make outpatient surgery more convenient and cost-effective the the hospital campus setting, for which the proposed OR capacity will primarily serve as a substitute.

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

The estimated total project budget to complete the project is approximately $10.4 million, which the applicant will fund with cash. The project budget is shown in Table III-7.

Table III-7: Children's National of Prince George's County Project Budget for ASF Component

Use of Funds	Total
Renovations	
Building	$3,210,000
Fixed equipment	856,000
Architect/engineering fees	246,100
Permits (building, utilities, etc.)	32,100
Subtotal	$4,344,200
Other Capital Costs	
Movable equipment	$5,672,255
Contingency allowance	325,815
Subtotal	$5,998,070
Total Capital Costs	**$10,342,270**
Expenses related to the CON application	57,200
Total Uses of Funds	**$10,399,470**
Sources of Funds	
Cash	**$10,399,470**

Source: DI #25, Exh. 37.

The applicant provided financial statements audited by PriceWaterhouseCoopers LLP that show that Children's National Medical Center has access to the cash necessary to fund this project. (DI #2, Exh. 20).

Availability of Resources to Sustain the Proposed Project

Children's Hospital's projected operating results are shown in Table III-8 below. The applicant projects that it will not generate income in the first two years of operation, but will generate income by the third year as the project ramps up to a higher level of use. Salaries and expenses for supplies are projected to increase concomitant with increased patient volume. Additional project expenses include depreciation costs, and other expenses such as malpractice insurance, minor moveable equipment, maintenance, utilities, and lease expenses. (DI #2, p. 57).

Table III-8: Children's National of Prince George's County Revenue & Expense Statement, CY 2020 - CY 2023

	CY 2020	CY 2021	CY 2022	CY 2023
Revenues				
Gross Revenues	$12,142,499	$13,856,411	$25,316,997	$26,141,125
Allowance for Bad Debt	202,032	230,549	421,188	434,850
Contractual Allowance	7,818,767	8,922,384	16,300,213	16,828,951
Charity Care	98,561	112,473	205,476	212,141
Net Operating Revenue	***$4,023,139***	***$4,591,005***	***$8,390,120***	***$8,665,183***
Expenses				
Salaries & Wages	2,908,647	3,272,672	5,153,512	5,306,884
Contractual Services	20,249	20,775	21,274	21,806
Project Depreciation	1,169,321	1,169,321	1,169,321	1,169,321
Supplies	391,926	447,246	817,162	843,762
Other Expenses*	311,681	567,886	618,349	623,643
Total Operating Expenses	***$4,801,823***	***$5,577,880***	***$7,779,617***	***$7,965,416***
Net Income	***$(778,684)***	***$(986,875)***	***$610,503***	***$699,767***

* Includes minor equipment, maintenance, lease and rental expenses, utilities, and other miscellaneous expenses.

Source: DI #2, pp. 56-57; DI #25, Exh. 38.

The proposed ASF is projected to require 27.3 full-time equivalent ("FTE" employees, including two nurse administrators, 6.6 physicians, 9 nurses, 2.3 technicians, and 7.5 support staff. These staffing levels are based on the applicant's experience at its existing Montgomery County ASF. (DI #2, Exhibit 19).

Staff concludes 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.

The Commission issued a Certificate of Need (Docket No. 04-15-2151) in September 2005 to CNMC to add a second sterile operating room to Children's Outpatient Center at Montgomery County (located at 9850 Key West Avenue in Rockville), thereby establishing an ambulatory surgical facility. In March 2006, the Commission issued a modification for changes related to design, circulation, and patient safety regarding the second operating room. While these changes "were not considered changes to the fundamental nature of the approved facility," the applicant needed Commission approval for the capital cost increases (about 24%) which exceeded the approved capital cost inflated by 7.2 percent per year.[9]

[9] The standard used in 2006 for project cost increases was different from the inflation-indexed standard currently in use

Taking into account this modification, staff concludes that the 2005 project was implemented in compliance with all terms and conditions of its CON. (DI #2, p. 60).

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 Surgical Services Chapter includes guidance for assessing the impact of a new ambulatory surgery center on a hospital, but does not provide similar guidance to assess the impact on existing ambulatory surgical facilities. The guidance for hospitals dictates that if the needs assessment includes surgical cases performed by one or more physicians who currently perform cases at a hospital within the defined service area of the proposed ambulatory surgical facility that, in the aggregate, account for 18% of the operating room capacity at a hospital, then the applicant shall include, as part of the impact assessment, a projection of the levels of use at the affected hospital for at least three years following the anticipated opening of the proposed ambulatory surgical facility.

The applicant expects 14 surgeons who currently operate within the CNMC network to begin providing services at the proposed ASF. The applicant reported that 9,841 total same day surgery cases were performed at the main hospital campus in FY 2017. The applicant projected that existing surgeons will perform 1,229 surgical cases at the ASF in Year 1, or what would amount to 12.5% of the hospital's FY 2017 ambulatory surgery cases. By Year 3, CH projects that the proposed ASF will redirect more than 2,126 cases from its existing same day surgery workload at the main campus, but that the impact on CNMC will be positive because the proposed project will help address capacity constraints at the hospital, providing the hospital additional capacity to support more complex cases and address increased demand from the growing populations in the District of Columbia and Virginia within the network's service area, which has grown by 18% between 2010 and 2017, according to the U.S. Census, as shown in Table III-9. (DI #2, pp. 36-38, 62).

In addition to that population data provided by the applicant, MHCC staff researched the change in the pediatric (0-19) population in the Maryland counties in the applicant's primary and secondary service area (Table III-10). The pediatric population in that section of the applicant's service area grew much more modestly during that period (1.8%).

Table III-9: Population Estimates and Growth Rate for the District of Columbia and Selected Jurisdictions in Virginia Population Under 18 Years, 2010-2017

	2010	2017	Population Change	% Change
District of Columbia	**101,265**	**124,492**	**23,227**	**22.9%**
Alexandria City	24,233	28,866	4,633	19.1%
Fairfax City	4,621	5,739	1,118	24.2%
Arlington	33,126	41,976	8,850	26.7%
Fairfax	263,558	269,030	5,472	2.1%
Fauquier	16,450	16,253	-197	-1.2%
Loudon	96,294	113,312	17,018	17.7%
Prince William	117,173	126,361	9,188	7.8%
Stafford	37,246	38,437	1,191	3.2%
Total Virginia Jurisdictions	**592,701**	**639,974**	**47,273**	**8.0%**
Total D.C. and Virginia	**693,966**	**764,466**	**70,500**	**18.2%**

Source: U.S. Census Bureau, Population Division. Annual Estimates of the Resident Population for Selected Age Groups by Sex for the United States, States, Counties and Puerto Rico Commonwealth and Municipios: April 1, 2010 to July 1, 2017 (release d: June 2018).

Table III-10: Population Estimates for the Maryland Portions of the Service Area

	2010	2017
Primary		
Prince George's	236,408	230,024
Anne Arundel	138,268	140,612
Charles	42,920	42,585
St. Mary's	30,795	30,642
Calvert	25,527	23,629
Total MD Primary	473,918	467,492
Secondary		
Montgomery	252,557	268,868
Howard	80,723	85,850
Total MD Secondary	333,280	354,718
Maryland Total	807,198	822,210

Source: United States Census Bureau American Fact Finder (https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src)

The applicant states that the project will not adversely impact other ASFs in its projected service area. CH provided a list of existing ASFs in Prince George's, Anne Arundel, Calvert, Charles, and St. Mary's Counties showing their volumes of pediatric patients over the previous seven-year period.[10] According to this data, just 25 of the 95 existing ASFs or surgery centers in the proposed project's primary service area performed pediatric surgical procedures. Of these, six reported performing 10% or more of its total cases on pediatric patients. After analyzing each facility, the applicant concluded that its proposed ASF will not have a significant impact on any of these existing providers. CH summarizes its impact on these providers as follows.

- Hotchkiss and Katzen Ambulatory Surgery Center in Prince George's County and MedSurg Foot Center in Anne Arundel County are podiatric specialty surgery centers. CH does not plan to have any podiatrists performing surgery in the proposed ASF.

[10] CH sourced this information from the MHCC public use data files.

- Oxon Hill Urology Surgery Center in Prince George's County, which reported 13% of cases performed on patients aged 0-14, is a physician-owned single-specialty urology center with one procedure room. CH projects that its urological surgery cases will be drawn from existing volume that migrates from the CNMC campus.
- In Anne Arundel County, Annapolis ENT most recently reported 56% of cases performed on patients aged 0-14 in FY 2015 and Piney Orchard Surgery Center LLC reported 36% of cases performed on patients aged 0-14 that year. According to the applicant, these ASFs provide a lower level of otolaryngological surgery, while CH projects that its ear, nose, and throat case volume will migrate from the CNMC campus.
- Finally, Arundel Ambulatory Surgery Center in Anne Arundel County, which reported 10% of cases performed on patients aged 0-14, is a multi-specialty surgery center with two operating rooms. Since Children's projected most of its volume from migration, it believes that it will not have a significant impact on this ASF. (DI #25, pp. 112-113).

<u>Impact on access to health care services, system costs, and costs and charges of other providers</u>

The applicant states that the establishment of its proposed two-OR ASF will not impact overall payor mix. It states that most cases are projected to migrate from existing network resources, and that additional volume will be driven by increased demand that will reflect the current mix. The applicant notes that other providers may experience minimal volume impact, but there should be no measurable impact on their payor mix or charges. (DI #2, p. 65; DI #25, pp. 112-113).

CH believes that its establishment of the proposed ASF within the Children's network will increase patient access in Prince George's County and surrounding counties. It notes that the location is accessible by public transportation and will likely improve access and satisfaction for Medicaid patients with transportation issues who receive ongoing and follow up care. The applicant states that the project will also benefit self-pay patients and those with high deductibles because an ambulatory surgical facility option is less costly than receiving hospital-based outpatient surgery. (DI #2, p. 65).

Staff concludes that the applicant thoroughly assessed the likely impact of its proposed project. The applicant is a hospital that will forfeit existing volume as a result of the project, but the shifting of these cases will provide the hospital with an opportunity to serve more complex cases and meet the growing demand emanating from population growth in other parts of its own service area. The impact to other providers should be minimal. The project is likely to have a positive impact on system costs because cases will be redirected from the CNMC hospital setting to its ASF. CH's establishment of Children's National of Prince George's County will provide a more accessible location for many Maryland residents for pediatric ambulatory surgery. Staff concludes that the overall impact of this project, as defined in this criterion, will be positive.

IV. SUMMARY AND STAFF RECOMMENDATION

Based on its review of the proposed project's consistency with the Certificate of Need review criteria (COMAR 10.24.01.08G(3)(a)-(f)) 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 authorize a Certificate of Need for the project. The project complies with the applicable State Health Plan standards, is needed, is a cost-effective approach to meeting the project objectives, is viable, will have a positive impact on the applicant's ability to provide outpatient surgery without adversely affecting costs and charges or other providers of surgical care, and will benefit service area residents who will not travel as far to receive pediatric surgery services.

Accordingly, Staff recommends that the Commission **APPROVE** Children's Hospital's application for a Certificate of Need authorizing the addition of a two-operating room ASF at its Regional Outpatient Center in Prince George's County with the following conditions:

1. The ambulatory surgical facility at Children's National of Prince George's County shall maintain compliance with the provisions of COMAR 10.24.16.08E(1)-(4) regarding charity care; and

2. The ambulatory surgical facility at Children's National of Prince George's County shall provide an amount of charity care equivalent to 0.56% of its operating expenses.

IN THE MATTER OF	*	BEFORE THE
	*	
CHILDREN'S HOSPITAL	*	MARYLAND HEALTH
	*	
Docket No. 18-16-2413	*	CARE COMMISSION
	*	

* *

FINAL ORDER

Based on the analysis and conclusions contained in the Staff Report and Recommendation, it is this 20th day of September, 2018, by a majority of the Maryland Health Care Commission, **ORDERED:**

That the application by Children's Hospital for a Certificate of Need to establish a two-operating room ambulatory surgical facility at 2900 North Campus Way, in Glenarden in Prince George's County, at an estimated cost of $10,399,470, is hereby **APPROVED**, subject to the following conditions:

1. The ambulatory surgical facility at Children's National of Prince George's County shall maintain compliance with the provisions of COMAR 10.24.16.08E(1)-(4) regarding charity care; and

2. The ambulatory surgical facility at Children's National of Prince George's County shall provide an amount of charity care equivalent to 0.56% of its operating expenses.

MARYLAND HEALTH CARE COMMISSION

MARYLAND HEALTH CARE COMMISSION

APPENDIX 1: Record of the Review

Docket Item #	Description	Date
1	Commission staff acknowledged Children's National's intent to file Certificate of Need.	11/7//2017
2	Michael Rovinsky, MBA, of Veralon Healthcare Management Advisors, submitted a Certificate of Need application on behalf of Children's Hospital, proposing the development of a 2 OR ASF (Matter No. 18-16-2413) located in Prince George's County, Maryland.	1/5/2018
3	Commission acknowledged receipt of CON application.	1/10/2018
4	Commission requested publication of notification of receipt of the Children's National's proposal in the *Washington Times.*	1/10/2018
5	Commission requested publication of notification of receipt of the Children's National's proposal in the *Maryland Register*.	1/10/2018
6	The *Washington Times* provided the notice of the receipt of application that published.	1/19/2018
7	Following completeness review, Commission staff found the application incomplete, and requested additional information.	3/1/2018
8	Applicant requested and Commission staff approved an extension to file completeness questions until 3/22/2018.	3/12/2018
9	Commission received responses to the request for additional information.	3/22/2018
10	Commission notified Children's National that its application is docketed for formal review on April 13, 2018.	3/30/2018
11	Commission requested publication of notice of formal start of review for the Children's National proposal in the *Washington Times*.	3/30/2018
12	Commission requested publication of the notice of formal start of review in the *Maryland Register.*	3/30/2018
13	Commission sent copy of the application to the Prince George's Health Department for review and comment.	3/30/2018
14	Commission receives notification of the formal start of review for Children's National as published in the *Washington Times*.	4/19/2018
15	Commission Staff requested additional information responses.	5/31/2018
16	Applicant requested, and Staff granted, extension to file additional information until 6/22/18.	6/8/2018
17	Applicant requested, and Staff granted, extension to file additional information until 6/29/18.	6/20/2018
18	Applicant filed preliminary response to request for additional information.	6/21/2018
19	Commission Staff provided clarification on requirements for applicant's charity care policy via email.	6/28/2018
20	Applicant filed response to request for additional information.	6/29/2018
21	Applicant filed response for additional supplemental information.	7/2/2018
22	Commission Staff provided clarification on supplemental information via email.	7/5/2018
23	Commission Staff requested additional information response.	7/17/2018
24	Applicant requested, and Staff granted, extension to file additional information until 8/7/18.	7/26/2018
25	Applicant filed additional information response.	8/7/2018
26	Applicant requested, and Commission provided, guidance on completeness request Question 12, via email.	8/13/18
27	Applicant filed additional information response.	8/21/18

MARYLAND HEALTH CARE COMMISSION

APPENDIX 2:

Excerpted CON Standards for General Surgical Services
From State Health Plan Chapter 10.24.11

Excerpted 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.

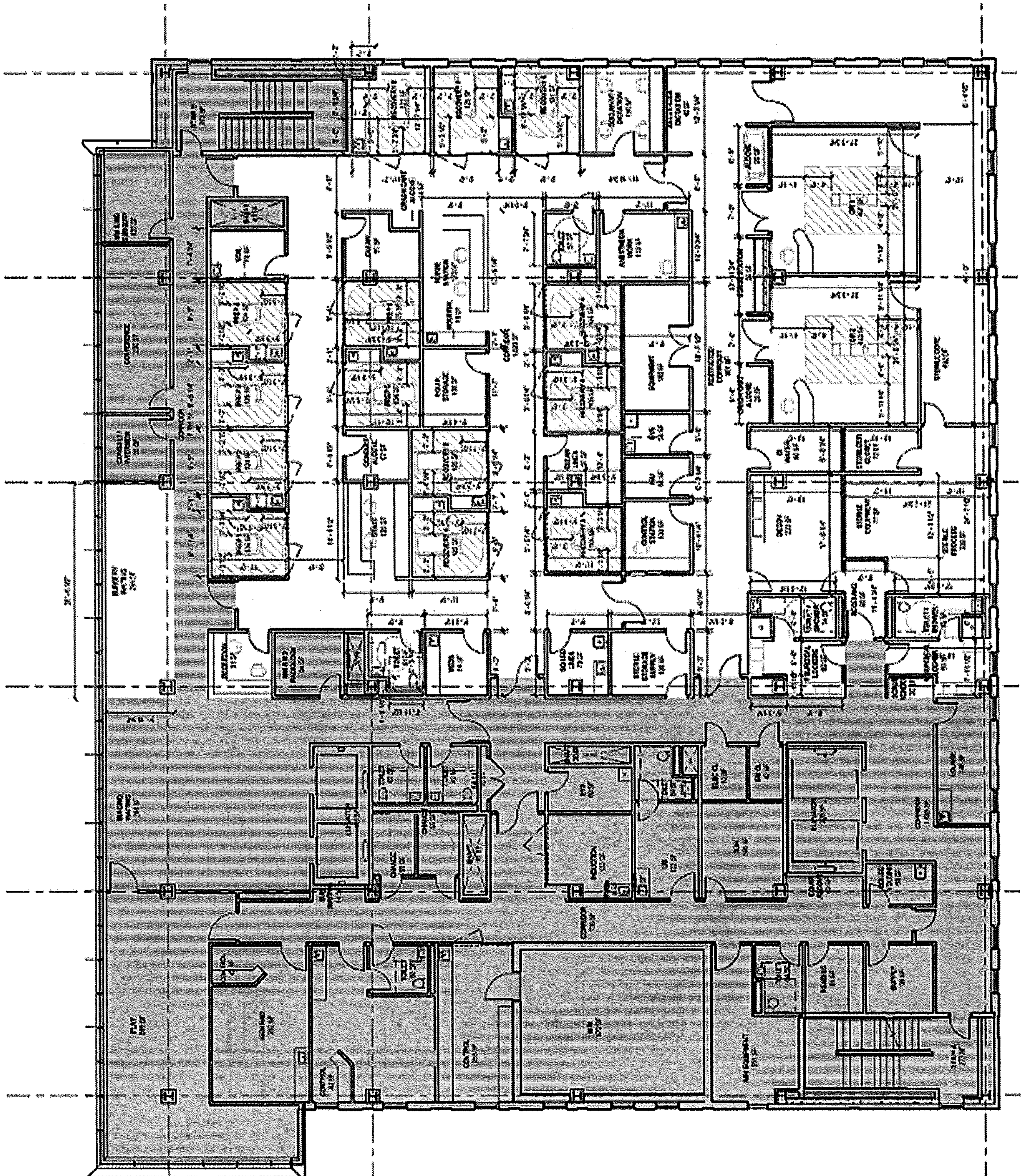
STANDARD	APPLICATION REFERENCE (Docket Item #)
.05A(3) Quality of Care A facility providing surgical services shall provide high quality care. (a) An existing hospital or ambulatory surgical facility shall document that it is licensed, in good standing, by the Maryland Department of Health and Mental Hygiene. (c) An existing ambulatory surgical facility shall document that it is: (i) In compliance with the conditions of participation of the Medicare and Medicaid programs; and (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. (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. (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, pp. 26-27
.05A(4) Transfer Agreements.	DI #9, Exh. 23

(a) Each ASF and hospital shall have written transfer and referral agreements with hospitals capable of managing cases that exceed the capabilities of the ASF or hospital. (b) Written transfer agreements between hospitals shall comply with the Department of Health and Mental Hygiene 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.	
.05B(4) <u>Design Requirements</u>. Floor plans submitted by an applicant must be consistent with the current FGI Guidelines. (a) A hospital shall meet the requirements in Section 2.2 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, Exh. 17
.05B(5) <u>Support Services</u>. Each applicant shall agree to provide as needed, either directly or through contractual agreements, laboratory, radiology, and pathology services.	DI #2, p. 42

MARYLAND HEALTH CARE COMMISSION

APPENDIX 3:

Project Floor Plans



MARYLAND HEALTH CARE COMMISSION

APPENDIX 4:

Marshall Valuation Service Review

Marshall Valuation Service Review

The Marshall Valuation System – what it is, 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 <u>do not include</u> 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 cost 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.[11]

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 (e.g., an add-on for sprinkler systems, the presence or absence of elevators, number of building stories, the height per story, and the shape of the building. The base cost is also adjusted to the latest month and the locality of the construction project.)

Calculating the Adjusted Project Cost in this Application

PG ROC states that the proposed ASF "will be located in a leased building that is otherwise being constructed as a medical office building ("MOB"). The cost of constructing the proposed PGC ASF is, therefore, assumed to be similar to that of renovating shell space in an existing MOB." (DI #9, p. 82).

PGC ROC and MHCC staff calculated the adjusted project cost per sq. ft. based on the actual costs of renovating 10,700 sq. ft., excluding those costs categorized in the introduction above. Table A below shows the calculations of the adjusted project cost made by the applicant and by MHCC.

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[11] Marshall Valuation Service Guidelines, Section 1, p. 3 (January 2016).

Table A: Respective Adjusted Project Cost Developed by PGC ROC and MHCC Staff

Cost of New Addition	
New Construction	
Building	$3,210,000
Fixed Equipment	0
Normal Site Preparation	0
Architect/Engineering	160,000
Permits	9,630
Capitalized Construction Interest	0
Financing Fees	0
Project Costs for MVS Comparison	$3,379,630
Square Feet of Construction	10,700
Adjusted Project Cost per SF	$315.85
MVS Cost/SF	$304.95
Over(Under)	$10.90

Source: DI #9, p.Table B, p. 84.

PG ROC and MHCC did not differ in the adjusted project costs used for the MVS comparison.

<u>**Developing an MVS Benchmark for This Project**</u>

PG ROC calculated the benchmark to be $309.28 per sq. ft. using the CoreLogic Swift Estimator Commercial Estimator software package to calculate a base cost for good quality Class A construction of an outpatient surgical center ("OSC") of $441.36 per sq. ft. (DI #9, p. 82). The applicant used the following assumptions:

1. The applicant states that "the building cost of about $3.2 million (submitted in Table E) includes costs to build-out an ASF in a base building delivered as a warm shell, designed and constructed to suit fit-out of a medical office building ("MOB")." (DI #9, p. 81)
2. Since the applicant used the Perimeter Multiplier; Height Multiplier; and Sprinklers in the calculations for the ASF/OSC and the MOB, the applicant assumed a value of one (1).
3. Since both the proposed ASF/OSC and the MOB are no higher than three stories, the applicant used a Multi-Story Multiplier of one (1).
4. While the applicant states the Update (Current Cost Multiplier) and Local Multiplier should both be 1.06 based on the project's location by zip code, PG ROC did not use this value and instead used a one (1) for both multipliers, as indicated in Table B below.
5. Since the applicant states that "the area of the MOB in which the proposed PGC ASF will be located (should) be considered shell space," a Departmental Cost Differentiation factor of 0.5 for this "unassigned space" was used.

MHCC staff calculated an MVS benchmark of $304.95 per sq. ft. by adjusting the MVS base cost ($379.00 per sq. ft. as of November 2017) for outpatient surgical centers used by the applicant as follows:

1. Use of a departmental cost factor of 1.00 for an operating room suite that includes the construction of supporting spaces such as a nursing station, preparation and recovery rooms, and equipment storage as well as two new operating rooms.
2. Since the ASF includes the fit-out of 10,700 sq. ft. with the perimeter size for the construction site of 492 linear feet, MVS calculates the Perimeter Multiplier is 0.965.
3. With the height for the ASF at 16 ft, 6 inches, MVS indicates the Height Multiplier is 1.1196.
4. The cost of installing a wet sprinkler system for the entire 60,000 sq. ft. MOB is estimated at $3.28 per sq. ft.
5. Staff updated the square foot cost as of August 2018 by applying the MVS Current Cost Multiplier of 1.04 for Class A-B health care building.
6. Staff then adjusted the cost to the location of the project by applying the MVS Local Multiplier for Silver Spring (1.05) as of July 2018 (the most current available) to arrive at an initial benchmark square foot cost of $447.17 per sq. ft. if this project was for totally new construction in this space.
7. As a last step to account for the fact that the project involves the fit-out for an ambulatory surgery facility in a newly constructed medical office building, staff subtracted a benchmark for the construction of outpatient surgical shell space ($142.22 per sq. ft. from the initial benchmark of $447.17 per sq. ft.) for a final benchmark for this project of $304.95 per sq. ft. Staff calculated the benchmark for constructing the shell space by applying the hospital departmental cost factor for vacant space (0.5) to the base cost for an outpatient surgical center and then applying the same multipliers as used in calculating the initial benchmark.

The following table identifies select building characteristics, the MVS base cost and the adjustments and calculations made by PGC ROC and MHCC staff for this analysis:

Table B: Marshall Valuation Services Benchmark - PGC ROC and MHCC Staff's Calculations

	PG ROC		MHCC	
Class	A		A-B	
Type	Good		Good	
Perimeter (ft.)	492'		492'	
Wall Height (ft.)	16' 6"		16' 6"	
Stories	3		1	
Average Area Per Floor (sq. ft.)	10,700		10,700	
	OSC	MOB	ASC	MOB
Net Base Cost	$441.36	$264.16	$379.00	$235.00
Elevator Add-on	0	0	0	0
Adjusted Base Cost	$441.36	$264.16	$379.00	$235.00
Departmental Cost Diff.	1	0.5	1	0.5
Gross Base Cost	$441.36	$132.08	$379.00	$117.50
Perimeter Multiplier	1	1	0.965	0.965
Story Height Multiplier	1	1	1.1196	1.1196
Multi-story Multiplier	1	1	1	1
Multipliers	1.000	1.000	1.080	1.080
Refined Square Foot Cost	$441.36	$132.08	$409.49	$126.95
Sprinkler Add-on (wet)	0	0	0	3.28
Adjusted Refined Square Foot Cost	$441.36	$132.08	$409.49	$130.24
Current Cost Modifier	1	1	1.04	1.04
Local Multiplier	1	1	1.05	1.05
CC & Local Multipliers	1.000	1.000	1.092	1.092
MVS Building Cost Per Square Foot	$441.36	$132.08	$447.17	$142.22
PG ROC MVS Building Cost Per Square Foot	$ 309.28		$ 304.95	

Source: DI #9, 81 - 84.

The difference in the MVS Benchmark values calculated by the applicant and MHCC staff is $4.33 per sq. ft., about 1.4% difference. The major reason for PG ROC's higher benchmark is the higher Net Base Cost values that the applicant used for both the OSC and the MOB. While the applicant's Perimeter Multiplier (1) was higher than the one used by MHCC (0.965), this one factor was offset by the higher values used by staff for the Story-Height Multiplier, Current Cost Modifier, and Local Multipliers, as well as the Sprinkler Add-on for the MOB. Both the applicant and MHCC adjusted the benchmark MVS Building Cost each calculated for new construction by subtracting the cost of shell space from the cost of constructing the ASC. While CoreLogic is the owner of both the Marshall Swift Valuation System used by MHCC and the Swift Estimator Commercial Estimator software package used by PG ROC, staff does not know the basis for the higher Net Base Cost values, and cannot provide an explanation for the higher values used by PG ROC for the OSC and the MOB.

Comparing Estimated Project to the MVS Benchmark

MHCC staff's analysis found the estimated project cost to be $10.90 per sq. ft. (about 3.6%) over the calculated MVS benchmark, while PGC ROC calculated the project costs to be $6.57 per sq. ft. (about 2.1%) over the MVS benchmark.

Table C: Comparison of Adjusted Project Cost as Calculated with the MVS Benchmark

	PGC ROC Calculation	MHCC Staff Calculation
Adjusted Project Cost per SF	$ 315.85	$ 315.85
PGC ROC and MHCC calculated MVS Benchmark Cost per SF	$ 309.28	$ 304.95
Total Over (Under) MVS Benchmark	$ 6.57	$ 10.90
Over(Under) %	**2.1%**	**3.6%**

Source: DI #9, p. 81 - 84 and MHCC Staff calculations