Children's National

Prince George's County

Ambulatory Surgery Facility

Certificate of Need Application

Submitted to the Maryland Health Care Commission

January 5, 2018

VERALON
HEALTHCARE MANAGEMENT ADVISORS

January 5, 2018

Via Email and Hand Delivery
(ruby.potter@maryland.gov)

Ms. Ruby Potter
Health Facilities Coordinator
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Dear Ms. Potter:

On behalf of Children's Hospital, a subsidiary of Children's National Medical Center, Inc., enclosed please find six copies of the Certificate of Need (CON) application for development of an ambulatory surgery facility (ASF) in Prince George's County, MD. A copy of the application, in both searchable printable data file (PDF) and Microsoft Word formats, along with native formats of spreadsheets and other files, will be provided to you by e-mail.

We appreciate your consideration of the application, and welcome any questions that you may have.

Sincerely,

Michael Rovinsky, MBA
Director

Enclosures

cc: Kevin McDonald, Maryland Health Care Commission
Charles Weinstein, Children's National Medical Center, Inc.

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PART I - PROJECT IDENTIFICATION AND GENERAL INFORMATION

1. FACILITY

Name of Facility: Children's National of Prince George's County

Address:

Street	City	Zip	County
2900 North Campus Way	Glenarden	20706	Prince George's County

2. Name of Owner: Children's National Medical Center, Inc.

If Owner is a Corporation, Partnership, or Limited Liability Company, attach a description of the ownership structure identifying all individuals that have or will have at least a 5% ownership share in the applicant and any related parent entities. Attach a chart that completely delineates this ownership structure.

Children's Hospital, a subsidiary of Children's National Medical Center, Inc., will be the sole owner of the Proposed Facility. A copy of Children's organizational chart is provided in Exhibit 1

3. APPLICANT. *If the application has a co-applicant, provide the following information in an attachment.*

Legal Name of Project Applicant (Licensee or Proposed Licensee):

Children's Hospital, a subsidiary of Children's National Medical Center, Inc.

Address:

111 Michigan Ave., NW	Washington	20010	D.C.	N/A
	City	**Zip**	**State**	**County**
Telephone:	(202) 476-4000			

4. NAME OF LICENSEE OR PROPOSED LICENSEE, if different from the applicant:

Not applicable.

5. LEGAL STRUCTURE OF APPLICANT (and LICENSEE, if different from applicant).

Check ☑ or fill in applicable information below and attach an organizational chart showing the owners of applicant (and licensee, if different).

A.	Governmental	☐	
B.	Corporation		
	(1) Non-profit	☒	
	(2) For-profit	☐	
	(3) Close	☐	State & Date of Incorporation
C.	Partnership		
	General	☐	
	Limited	☐	
	Limited Liability Partnership	☐	
	Limited Liability Limited Partnership	☐	
	Other (Specify):		
D.	Limited Liability Company	☐	
E.	Other (Specify):		
	To be formed:	☐	
	Existing:	☐	

6. PERSON(S) TO WHOM QUESTIONS REGARDING THIS APPLICATION SHOULD BE DIRECTED

A. Lead or primary contact:

Name and Title: Charles Weinstein, Esq.
Executive Vice President and Chief Real Estate and Facility Officer

Company Name Children's National Medical Center, Inc.

Mailing Address:

111 Michigan Ave., NW	Washington	20010	D.C.
Street	**City**	**Zip**	**State**

Telephone: (202) 476-6375

E-mail Address (required): charles.weinstein@childrensnational.org

Fax: N/A

If company name is different than applicant briefly describe the relationship	The applicant, Children's Hospital, is a subsidiary of Children's National Medical Center, Inc.

B. Additional or alternate contact:

Name and Title: Denise Cora-Bramble, MD, MBA
Chief Medical Officer & Executive Vice President, Ambulatory & Community Services

Company Name Children's National Medical Center, Inc.

Mailing Address:

111 Michigan Ave., NW	Washington	20010	D.C.
Street	**City**	**Zip**	**State**

Telephone: (202) 476-5857

E-mail Address (required): dcorabra@childrensnational.org

Fax: N/A

If company name is different than applicant briefly describe the relationship	The applicant, Children's Hospital, is a subsidiary of Children's National Medical Center, Inc.

Name and Title: Michael Rovinsky, MBA
Director

Company Name Veralon Partners Inc.

Mailing Address:

1628 John F. Kennedy Blvd., Ste. 500	Philadelphia	19103	PA
Street	**City**	**Zip**	**State**

Telephone: (404) 334-4663

E-mail Address (required): mrovinsky@veralon.com

Fax: N/A

If company name is different than applicant briefly describe the relationship	Veralon Partners Inc. ("Veralon") was engaged by Children's National Medical Center, Inc. to assist with preparation and submission of this application.

7. TYPE OF PROJECT

The following list includes all project categories that require a CON pursuant to COMAR 10.24.01.02(A). Please mark all that apply in the list below.

If approved, this CON would result in (check as many as apply):

(1) A new health care facility built, developed, or established ☒
(2) An existing health care facility moved to another site ☐
(3) A change in the bed capacity of a health care facility ☐
(4) A change in the type or scope of any health care service offered by a health care facility ☐
(5) A health care facility making a capital expenditure that exceeds the current threshold for capital expenditures found at: http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/documents/con_capital_threshold_20140301.pdf ☐

8. PROJECT DESCRIPTION

A. Executive Summary of the Project: The purpose of this BRIEF executive summary is to convey to the reader a holistic understanding of the proposed project: what it is, why you need to do it, and what it will cost. A one-page response will suffice. Please include:

(1) Brief Description of the project – what the applicant proposes to do
(2) Rationale for the project – the need and/or business case for the proposed project
(3) Cost – the total cost of implementing the proposed project

Children's Hospital, a subsidiary of Children's National Medical Center, Inc., ("Children's"), seeks to establish an ambulatory surgery facility (ASF) with two (2) operating rooms as part of a new 60,000 square foot regional outpatient center (ROC) to be built in Prince George's County, Maryland (the "PGC ROC"). The PGC ROC (and the proposed ASF) will be located at 2900 N. Campus Way, Glenarden, MD 20706.

The new PGC ROC is a key component of Children's ambulatory services strategy and supports the facility master plan at the main Children's campus in Washington, DC. Children's currently operates two outpatient centers in Prince George's County: one in Laurel, and one in Upper Marlboro. The PGC ROC will serve to consolidate and replace these two existing centers and supplement the services offered at the centers with additional pediatric specialty and sub-specialty services that are currently primarily available at the hospital. The PGC ROC will serve as Children's flagship ambulatory service location to serve children and their families from the eastern and southern portions of central Maryland.

The PGC ROC will house a wide range of pediatric sub-specialists, including physicians who currently practice at the two existing outpatient centers located in Prince George's County as well as new physicians to be recruited by Children's. Pediatric surgical sub-specialties to be offered at the PGC ROC include ENT, General Surgery, Gastroenterology, Ophthalmology, Plastic Surgery, Urology, and Orthopedics. The proposed new specialty pediatric ASF will offer these physicians, their patients, and their families a more convenient setting for care. In addition, anesthesiology for surgery performed at the new ASF will be provided by board-certified pediatric anesthesiologists, a distinct advantage in pediatric care over other ASFs in the service area that primarily serve adult patients. The facility will have child- and family-appropriate waiting areas and will be tailored to meet the unique needs of the

pediatric patient population and their families.

Additional details on the proposed project are provided in response to Question 8. B. below.

Children's is making a significant investment in the Prince George's County community that will not only care for the children in that county, but also the broader region as well. The new PGC ROC will represent a total investment of approximately $33 million. Costs specific to the proposed ASF are estimated to be approximately $10.4 million.

B. Comprehensive Project Description: The description should include details regarding:

(1) Construction, renovation, and demolition plans
(2) Changes in square footage of departments and units
(3) Physical plant or location changes
(4) Changes to affected services following completion of the project
(5) Outline the project schedule.

I. Introduction

Children's Hospital is the flagship hospital of Children's National Medical Center, Inc. Children's has been serving the nation's children for more than 145 years as an innovator in pediatric healthcare around the nation and around the world.

Children's was one of the nation's first children's hospitals, opening in 1870 and growing from a modest 12-bed facility to a 313-bed facility that performs approximately 17,000 surgeries and conducts more than 450,000 outpatient visits in more than 60 specialties each year. Children's is the only exclusive provider of pediatric care in the Washington, D.C. metropolitan area.

Today, Children's network includes primary care health centers, regional outpatient centers, and affiliated pediatric primary and specialty care practices throughout the metropolitan area, in addition to providing tertiary care on the main campus at Children's. Additionally, Children's is home to the Children's Research Institute and the Sheikh Zayed Institute for Pediatric Surgical Innovation, as well the Children's National Heart Institute, the Gilbert Family Neurofibromatosis Institute, the Brain Tumor Institute, and the Obesity Institute.

Throughout its history, Children's has witnessed tremendous growth and change in pediatric healthcare. The current healthcare marketplace is in the midst of unprecedented change, and Children's is committed to staying in front of the curve.

Institutes and Care Centers

Children's has established a variety of nationally recognized institutes, care centers, and specialty clinics that allow Children's clinicians and staff to collaborate on better ways to treat disease and nurture the whole child, including the following.

At the **Children's National Heart Institute** ("Heart Institute"), Children's expert pediatric cardiac team offers advanced heart care with excellent outcomes for thousands of children every year. Heart Institute specialties and programs include the following:

- Cardiology
- Cardiac Surgery
- Cardiac Anesthesiology
- Cardiac ICU
- Adult Congenital Heart Disease
- Fetal Heart Program

Children's **Center for Cancer and Blood Disorders** is a multi-disciplinary program that brings together specialists in the following areas:

- Blood and Marrow Transplantation
- Hematology
- Allergy and Immunology
- Laboratory Medicine/Oncology
- Pathology
- Pharmacology
- Rheumatology

At the **Joseph E. Robert, Jr., Center for Surgical Care**, more than 17,000 surgeries are performed each year. Children's pediatric surgical specialties include:

- Anesthesiology and Pain Medicine
- Trauma and Burns
- Gastroenterology
- General Surgery
- Ophthalmology
- Orthopedic Surgery and Sports Medicine
- Otolaryngology (ENT)
- Plastic and Reconstructive Surgery
- Urology

Children's **Rare Disease Institute** is a first-of-its-kind center focused exclusively on advancing the care and treatment of children and adults with rare genetic diseases. The Rare Disease Institute collaborates with a number of programs and services at Children's, including the following:

- Cancer Genetics
- Cardiogenetics
- Down Syndrome Clinic
- Fetal Medicine Institute
- Inherited Metabolic Disorders
- Lysosomal Storage Diseases
- Myelin Disorders
- Skeletal Dysplasia Clinic

Children's **Center for Neuroscience and Behavioral Health** houses the Daniel and Jennifer Gilbert Neurofibromatosis Institute and the Pediatric Brain Tumor Institute, internationally recognized centers for the care of and research on the minds, behaviors, emotions, and neurological functions of children. Divisions including the following:

- Neurology
- Neurosurgery
- Physical Medicine and Rehabilitation
- Psychiatry
- Psychology
- Neuropsychology
- Developmental Pediatrics
- Genetics
- Hearing and Speech

Children's **Center for Hospital-Based Specialties** is a hub for disciplines providing critical and acute care, as well as diagnostic and therapeutic imaging. It encompasses the following:

- Critical Care Medicine
- Diagnostic Imaging and Radiology
- Emergency Medicine
- Endocrinology and Diabetes
- Fetal Medicine Institute
- Hospitalist Medicine
- Infectious Disease
- Neonatology
- Respiratory Care
- Pulmonary
- Nephrology
- Transport Medicine

Finally, the **Diana L. and Stephen A. Goldberg Center for Community Pediatric Health** offers a community-based model focused on primary care, prevention, diagnosis, and treatment of pediatric health conditions. The center offers the following:

- Child and Adolescent Protection
- Dentistry
- Dermatology
- General and Community Pediatrics
- Adolescent and Young Adult Medicine
- Mobile Health

Children's Main Campus

Designed with kids' physical and emotional needs in mind, Children's main campus, the Sheikh Zayed Campus for Advanced Pediatric Medicine in Washington, D.C., is home to:

- Inpatient facilities with 313 beds.
- Outpatient clinics for all major services, with over 103,000 patient visits. (There were also over 86,000 visits to Children's off-campus outpatient locations, for a total of nearly 190,000 visits.)
- The Children's Research Institute, Children's academic arm, encompassing the translational, clinical, and community research efforts of the organization.
- The Sheikh Zayed Institute for Pediatric Surgical Innovation, transforming pediatric surgery and intervention.
- The Bear Institute Innovation and Learning Center, using information technology to develop new health solutions for young patients.

Primary Care Practices

Children's entire care team is composed of recognized experts in caring for children; it isn't just part of what Children's does, it's all Children's does. Primary care at Children's is available to children throughout the Washington, D.C. region through two comprehensive networks: The Children's National Health Centers or Children's Pediatricians & Associates.

<u>Children's National Health Centers</u>

There are six Children's National Health Centers located throughout Washington, D.C. CNHS' health centers are recognized as National Committee for Quality Assurance Level III Patient-Centered Medical Homes, the first in the District of Columbia.

Children's Pediatricians & Associates (CP&A)

With more than 50 providers in Washington, D.C. and Maryland, CP&A practices offer quality care at convenient locations. CP&A primary care providers also take a team approach to care for children. CP&A locations include:

- CP&A Capitol Hill in Washington, D.C.
- CP&A Foggy Bottom in Washington, D.C.
- CP&A Fort Davis in Washington, D.C.
- CP&A Bowie, MD
- CP&A Clinton, MD
- CP&A College Park, MD
- CP&A Laurel, MD
- CP&A Gaithersburg, MD
- CP&A Greenbelt, MD
- CP&A Silver Spring, MD
- CP&A Upper Marlboro, MD
- CP&A Waldorf, MD

Regional Outpatient Centers

Children's regional outpatient centers ("ROCs") provide increased access to expert, specialty care throughout Maryland, Virginia, and the District of Columbia. CNHS ROC's are currently located in the following areas:

- Annapolis, MD
- Laurel, MD
- Rockville, MD
- Upper Marlboro, MD
- Frederick, MD
- Fairfax, VA
- Washington, D.C. (Friendship Heights)

Additional Locations

Children's also offers care at other hospitals and outpatient centers throughout the region.

For example, Children's has partnered with United Medical Center to create the Children's National Emergency Department at United Medical Center. The 24/7 pediatric emergency facility provides urgent care and radiology services in the Southeast, D.C. hospital.

The Pediatric Specialists of Virginia, LLC is a joint venture between Inova and Children's that is dedicated exclusively to caring for children. The partnership ensures families in the region have access to the nation's most highly regarded doctors and experts devoted to pediatric care.

In addition, on November 17, 2016, Children's signed an agreement with the U.S. Army to accept the transfer of nearly 12 acres from the Walter Reed property in Northwest Washington, D.C. The 11.85-acre parcel, which nearly doubles the 12-acre footprint of Children's in Washington, includes four buildings:

- The former Armed Forces Institute of Pathology, a major research facility that encompasses about 348,000 square feet. The facility, in operation as recently as 7 years ago, was dedicated by President Eisenhower;
- A conference center and auditorium that can support Children's educational mission;
- A 31,000-square foot facility, most recently used as a clinic to treat Army soldiers on an outpatient basis; and
- An above ground parking garage.

Children's long-term vision for the Walter Reed campus is to create an internationally recognized medical research and innovation center, complemented by a pediatric primary care program that serves the surrounding community.

Specifically, the new campus will allow Children's to:

- Expand its world class pediatric research facilities through relocation to Walter Reed. Doing so will, in turn, allow expansion of key clinical care areas.
- Create an Innovation Center devoted to pediatrics, leveraging Children's unique location in the nation's capital and attracting the best and brightest research collaborators.
- Provide primary care services for pediatric and adolescent patients in the surrounding community. With the addition of this program, Children's will offer clinical services in every ward in the District of Columbia.

Additional information about Children's is provided in Exhibit 2.

The Prince George's County Regional Outpatient Center

Children's is developing a new 60,000 square foot Regional Outpatient Center in Glenarden, MD. The new PGC ROC is a key component of Children's ambulatory services strategy and supports the facility master plan at the main Children's campus in Washington, D.C. As indicated above, Children's currently operates two outpatient centers in Prince George's County: one in Laurel, and one in Upper Marlboro. The PGC ROC will serve to consolidate and replace these two existing centers and supplement the services offered at the centers with additional pediatric specialty and sub-specialty services that are currently primarily available at the hospital. The PGC ROC will serve as Children's flagship ambulatory service location to serve children and their families from the eastern and southern portions of central Maryland.

The development of the new ROC will serve two primary purposes:

1) It is essential, as the healthcare market transitions from volume-based fee-for-service reimbursement to value-based payment, that services be made more readily accessible and convenient for patients. Accessibility and convenience is especially important for the pediatric patient population, who are wholly dependent on their families for all aspects of care and recovery. Particularly given the severe traffic and congestion in and around the Washington, D.C. metropolitan area, it is critical that needed healthcare services, particularly outpatient services, are available close to the patient's (and family's) home.

2) Washington, D.C. and the surrounding communities served by Children's continue to grow. In addition, as care continues to shift from inpatient to outpatient settings, the acuity of patients in the inpatient setting continues to increase. These factors are contributing to a significant increase in demand for care at Children's main campus. Moving more ambulatory services from the main Children's campus to regional outpatient centers such as the PGC ROC will enable Children's to reserve space in the main hospital for the growing demand for inpatient pediatric care and alleviate capacity constraints on associated ancillary services, including,

but not limited to surgical capacity.

The PGC ROC will house a wide range of pediatric sub-specialists, including physicians who currently practice at the two existing outpatient centers located in Prince George's County, as well as new physicians to be recruited by Children's. Pediatric surgical sub-specialties to be offered at the PGC ROC include ENT, General Surgery, Gastroenterology, Ophthalmology, Plastic Surgery, Urology, and Orthopedics.

II. The Proposed Project

Children's is proposing to establish an ambulatory surgery center with two operating rooms as part of its new PGC ROC, to be located at 2900 N. Campus Way, Glenarden, MD 20706.

The proposed new specialty pediatric ASF will offer the physicians to be housed in the PGC ROC, their patients, and their families a more convenient setting for care. In addition, anesthesiology for surgery performed at the new ASF will be provided by board-certified pediatric anesthesiologists, a distinct advantage in pediatric care over other ASFs in the service area that primarily serve adult patients. The facility will have child and family appropriate waiting areas and will be tailored to meet the unique needs of the pediatric patient population and their families.

The existing surgeons who will be relocated to the PGC ROC currently perform most of their surgical cases at the main Children's campus. Traveling all the way from Prince George's County and the surrounding counties in Maryland to Children's main campus in the District of Columbia for outpatient surgical services is sub-optimal for care and recovery of pediatric patients and poses an unnecessary hardship on patients and their families. The availability of a two-operating room ASF in the PGC ROC will make care more accessible and convenient to the service area population in need of such services.

Initial planned surgical volumes will primarily be driven by a shift of patients from the Children's outpatient surgical unit at the main hospital in Washington D.C. Currently, approximately 58% of the surgeries at the main hospital location are performed on patients who reside in Maryland, and 34% are performed on patients from the proposed primary service area for the proposed ASF. Shifting a portion of these cases to this new ASF is not only convenient for patients, but it also allows Children's to free up capacity at the hospital operating rooms for more complex surgical cases that require additional specialty back-up and/or inpatient care.

Additionally, Children's anticipates substantial growth in surgical cases for patients residing closer to the main hospital campus, both in Washington, D.C. proper and in northern Virginia. Shifting a portion of the current surgical volume to the new ASF, closer to where the patients and their families live, will allow Children's to accommodate the expected growth in volume at the main hospital campus.

Future growth in surgical cases at the proposed ASF is to be driven by the recruitment of new surgeons to meet anticipated demand. This demand will come from pediatric population growth in the service area, the continued shift of cases from the inpatient to the outpatient setting, and some movement of pediatric surgical cases currently being performed in freestanding ASF's designed for and primarily serving adults to this more appropriate, highly specialized, pediatric surgery center.

III. Facility Description

The ASF will be housed within PGC ROC, designed as a state-of-the-art facility, with great consideration given to patient comfort and convenience. The proposed ASF will be located on the third floor of the ROC, along with an imaging center, administration, and staff support services. The functional layout of the ASF will be designed to facilitate the delivery of a quality surgical experience. The ASF will include two standardized, approximately 460 square foot operating rooms. The sterile processing department will support this facility and, potentially, additional off-site sterilization needs.

The design of the ROC supports a new workflow model which encourages sharing of many of the facility's clinical and support spaces between surgery and imaging. The shared use of check-in, waiting, prep and recovery, and storage/utility rooms will result in space, staff, and operational efficiencies, particularly associated with imaging patients who require complex preparation, anesthesia support, or post-procedural monitoring.

Specific components and features of the facility include the following:

1. **Waiting/Reception**: The waiting/reception area will be designed to promote efficient patient check-in and comfortable family waiting with separated areas for younger children and adolescents with designated play areas.

2. **Operating Rooms**: Two operating rooms will be designed "same handed" to standardize the location of equipment and supplies in the operating rooms. This approach will improve patient safety by eliminating a possible source of confusion and will also increase staff efficiency during surgical procedures. Standardized equipment will include equipment booms, LED lights, and in-room documentation areas to incorporate EMR.

3. **Preoperative Area**: Six cubicles with sliding door glass fronts will provide patient privacy during preparation for surgery while also accommodating family and consultation with nursing staff, the anesthesiologist, and the surgeon.

4. **Postoperative Area**: Eight post-anesthesia care unit (PACU) bay cubicles with sliding door glass fronts will provide patient privacy for pediatric patients and isolation. Bays will be located with direct visualization from the nurses' station to assure safe recovery from anesthesia.

5. **Central Sterile Processing**: Central sterile processing will provide full service instrument and scope sterilization for the ASF as well as for any other PGC ROC physician practices that utilize scopes or instruments (peel packs or sets). A specified process will be established for flow of instruments from dirty to clean through decontamination area to sterilization to clean storage of instruments. This one-way flow will reduce the potential of cross-contamination of sterile instruments.

7. **Sterile Core**: The sterile core will hold all surgical supplies and instrumentation for the operating rooms. This area will contain shelving for supplies and instrument sets and a staging area for pulling individual case totes prior to surgery (case carts are not utilized). An adjacent equipment storage room will provide equipment storage for the operating rooms, but will also be accessible to Pre-op/PACU and Imaging through a second doorway on the semi-restricted side.

8. **Staff Lounge/Lockers**: A staff lounge and lockers will offer a private area for staff changing and breaks between cases.

9. **Administrative Support/Office**: The facility will also include consult areas for private patient interview as well as business and management functions.

The entire ASF will encompass 10,700 square feet of space in the PGC ROC.

IV. Project Cost

Children's is making a significant investment in the Prince George's County community that will not only care for the children in that county, but the broader region as well. The new PGC ROC will represent a total investment of approximately $33 million. Costs specific to the proposed ASF are estimated to be approximately $10.4 million.

V. Project Schedule

As noted in Section 11B to follow, the construction of PGC ROC is scheduled to begin in June 2018 upon issuance of a grading permit by Prince George's County. The first phase of construction will involve site work and building foundations. Construction of the main building core and shell will then proceed, followed by tenant fit out/renovations including completion of the ambulatory surgery facility that is the subject of this application. No capital costs associated with the build-out of the ASF will be incurred prior to CON approval. The ASF is expected to achieve pre-licensure/first use by January 2020.

A more detailed construction schedule will be developed once a construction manager or general contractor is retained to manage the construction project.

9. Current Capacity and Proposed Changes:

Service	Unit Description	Currently Licensed/ Certified	Units to be Added or Reduced	Total Units if Project is Approved
Ambulatory Surgery	Operating Rooms	0	2	2
	Procedure Rooms	N/A	N/A	N/A

10. Identify any community based services that are or will be offered at the facility and explain how each one will be affected by the project.

No community based services related to the Proposed Project will be offered at the facility.

11. REQUIRED APPROVALS AND SITE CONTROL

A. Site size: **6.9494** acres

B. Have all necessary State and local land use and environmental approvals, including zoning and site plan, for the project as proposed been obtained? YES_____ NO __**X**___ (If NO, describe below the current status and timetable for receiving each of the necessary approvals.)

Zoning and site plan approval for PGC ROC is in place. The Landlord will obtain a certified site plan approval for on-lot development by April 2018. A building permit from Prince George's County will be required, which is anticipated to be obtained for the base building by May 2018 and for tenant improvements by August 2018. It is estimated that it will take approximately sixty to ninety days to obtain the permit, from date of submission.

C. Form of Site Control (Respond to the one that applies. If more than one, explain.):

(1) Owned by: WTC Lot 17, LLC

(2) Options to purchase held by: Children's Hospital

Please provide a copy of the purchase option as an attachment.

A copy of the lease agreement, including the purchase option, is included in Exhibit 3.

(3) Land Lease held by: N/A
Please provide a copy of the land lease as an attachment.

(4) Option to lease held by: N/A
Please provide a copy of the option to lease as an attachment.

(5) Other: N/A
Explain and provide legal documents as an attachment.

12. PROJECT SCHEDULE

(INSTRUCTION: IN COMPLETING THE APPLICABLE OF ITEMS 10, 11 or 12, PLEASE CONSULT THE PERFORMANCE REQUIREMENT TARGET DATES SET FORTH IN COMMISSION REGULATIONS, COMAR 10.24.01.12)

For new construction or renovation projects.

Project Implementation Target Dates

A.	Obligation of Capital Expenditure:	**1**	months from approval date.
B.	Beginning Construction:	**2**	months from capital obligation.
C.	Pre-Licensure/First Use:	**14**	months from capital obligation.
D.	Full Utilization:	**36**	months from first use.

For projects not involving construction or renovations.

Project Implementation Target Dates

A.	Obligation or expenditure of 51% of Capital Expenditure	**N/A**	months from CON approval date.
B.	Pre-Licensure/First Use	**N/A**	months from capital obligation.
C.	Full Utilization	**N/A**	months from first use.

For projects not involving capital expenditures.

Project Implementation Target Dates

A.	Obligation or expenditure of 51% Project Budget	**N/A**	months from CON approval date.
B.	Pre-Licensure/First Use	**N/A**	months from CON approval.
C.	Full Utilization	**N/A**	months from first use.

13. PROJECT DRAWINGS

Projects involving new construction and/or renovations should include scalable schematic drawings of the facility at least a 1/16” scale. Drawings should be completely legible and include dates.

These drawings should include the following before (existing) and after (proposed), as applicable:

A. Floor plans for each floor affected with all rooms labeled by purpose or function, number of beds, location of bath rooms, nursing stations, and any proposed space for future expansion to be constructed, but not finished at the completion of the project, labeled as “shell space”.

B. For projects involving new construction and/or site work a Plot Plan, showing the "footprint" and location of the facility before and after the project.

C. Specify dimensions and square footage of patient rooms.

Project drawings prepared to the prescribed scale are included as Exhibit 4.

14. FEATURES OF PROJECT CONSTRUCTION

A. If the project involves new construction or renovation, complete **Tables C and D of the Hospital CON Application Package**

Table C is included as Exhibit 5. Table D does not apply to the proposed project.

B. Discuss the availability and adequacy of utilities (water, electricity, sewage, natural gas, etc.) for the proposed project and identify the provider of each utility. Specify the steps that will be necessary to obtain utilities.

All utilities are available on-site for the proposed project through the following providers: • **Water**: Washington Suburban Sanitary Commission (WSSC) • **Electric**: Potomac Electric Power Company (PEPCO) • **Sewage**: Washington Suburban Sanitary Commission (WSSC) • **Natural Gas**: Washington Gas

PART II - PROJECT BUDGET

Complete Table E of the Hospital CON Application Package

Note: Applicant should include a list of all assumptions and specify what is included in each budget line, as well as the source of cost estimates and the manner in which all cost estimates are derived. Explain how the budgeted amount for contingencies was determined and why the amount budgeted is adequate for the project given the nature of the project and the current stage of design (i.e., schematic, working drawings, etc.).

Table E is included as Exhibit 6.

The following assumptions apply to the budget of the proposed project:

- **Line A.1.a(1) - Building**: ASF build-out costs were developed on a per square foot cost basis based on Children's experience on previous projects and the Project Manager's industry experience. The total build-out costs include landlord's contribution at $60/sf per lease agreement.

- **Line A.1.a(2) – Fixed Equipment: Equipment:** ASF fixed equipment cost is broken down to capture the cost of newly installed/fixed mechanical, electrical, and plumbing equipment. This cost was estimated based on equipment sizing provided by the project engineer as part of schematic design process.

- **Line A.1.a(4)– Architect/Engineering Fees:** Architect and engineering fees are based on the current agreement between Children's and the architectural and engineering firms being utilized for the proposed project.

- **Line A.1.a(5) – Permits:** Permit costs are based on discussions with the Prince George's County Department of Permitting, Inspections, and Enforcement.

- **Line A.1.c(1) – Moveable Equipment:** Equipment costs are based on figures provided by equipment consultants, Children's internal biomedical engineering department, user group input, and current equipment costs at other Children's facilities.

- **Line A.1.c(2) – Contingency:** Contingency has been carried on project hard and soft costs for design and construction, excluding equipment costs, at the rate of 7.5%, considering the stage of the project design.

- **Annual Lease Costs:** The lease agreement by and between WTC LOT 17, LLC and Children's Hospital for the PBC ROC is for an initial term of twenty (20) years. Annual rental cost in Year 1, which begins 180 days after the Rental Commencement Date, is $1,048,800. Beginning in Year 2, annual rental cost is $2,097,600, escalating 10% in Year 6 and every five (5) years thereafter. The weighted average annual lease cost is $2,381,328. Allocated on a square footage basis, the weighted average annual least cost for the proposed project is $461,598.

PART III - APPLICANT HISTORY, STATEMENT OF RESPONSIBILITY, AUTHORIZATION AND RELEASE OF INFORMATION, AND SIGNATURE

1. List names and addresses of all owners and individuals responsible for the proposed project and its implementation.

   Charles Weinstein, Esq.
   Executive Vice President and Chief Real Estate and Facility Officer
   Children's National Medical Center, Inc.
   111 Michigan Ave. NW
   Washington, D.C. 20010

2. Are the applicant, owners, or the responsible persons listed in response to Part 1, questions 2, 3, 4, 7, and 9 above now involved, or have they ever been involved, in the ownership, development, or management of another health care facility? If yes, provide a listing of these facilities, including facility name, address, and dates of involvement.

   As the Executive Vice President and Chief Real Estate and Facility Officer since July 2016, Charles Weinstein is involved in development of a variety of facilities with Children's. Past lease activity in which Mr. Weinstein has been involved since joining Children's to-date is provided in Exhibit 7.

   Projects currently underway on the Children's main campus in which Mr. Weinstein is currently involved include:
   - Vertical Transportation
   - Inpatient Psych Unit Renovation
   - Helipad Crew Support Renovation
   - Molecular Imaging
   - Chiller Plant Renovation
   - Healing Garden
   - Pharmacy USP 797-800 Compliance Renovation
   - Garage MEP Renovations
   - PICU Renovation
   - BMT Clinic Renovation
   - Cath Lab Renovation

   All are located at:
   Children's National Sheikh Zayed Campus
   111 Michigan Ave, NW
   Washington, D.C. 20010

   Facilities currently under development in the region in which Mr. Weinstein has been involved since joining Children's include:
   Regional Outpatient Center – Friendship Heights
   5028 Wisconsin Avenue NW
   Washington, D.C.

   Campus Dorchester Building
   12200 Plum Orchard Drive
   Silver Spring, MD

3. Has the Maryland license or certification of the applicant facility, or any of the facilities listed in response to Question 2, above, been suspended or revoked, or been subject to any disciplinary action (such as a ban on admissions) in the last 5 years? If yes, provide a

written explanation of the circumstances, including the date(s) of the actions and the disposition. If the applicant, owners or individuals responsible for implementation of the Project were not involved with the facility at the time a suspension, revocation, or disciplinary action took place, indicate in the explanation.

No.

4. Other than the licensure or certification actions described in the response to Question 3, above, has any facility with which any applicant is involved, or has any facility with which any applicant has in the past been involved (listed in response to Question 2, above) received inquiries in last from 10 years from any federal or state authority, the Joint Commission, or other regulatory body regarding possible non-compliance with any state, federal, or Joint Commission requirements for the provision of, the quality of, or the payment for health care services that have resulted in actions leading to the possibility of penalties, admission bans, probationary status, or other sanctions at the applicant facility or at any facility listed in response to Question 2? If yes, provide for each such instance, copies of any settlement reached, proposed findings or final findings of non-compliance and related documentation including reports of non-compliance, responses of the facility, and any final disposition or conclusions reached by the applicable authority.

No.

5. Have the applicant, owners or responsible individuals listed in response to Part 1, questions 2, 3, 4, 7, and 9, above, ever pled guilty to or been convicted of a criminal offense in any way connected with the ownership, development or management of the applicant facility or any of the health care facilities listed in response to Question 2, above? If yes, provide a written explanation of the circumstances, including as applicable the court, the date(s) of conviction(s), diversionary disposition(s) of any type, or guilty plea(s).

No.

One or more persons shall be officially authorized in writing by the applicant to sign for and act for the applicant for the project which is the subject of this application. Copies of this authorization shall be attached to the application. The undersigned is the owner(s), or Board-designated official of the proposed or existing facility.

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

January 4, 2018
Date

Signature of Owner or Board-designated Official

Executive Vice President and Chief Real Estate and Facility Officer
Position/Title

Charles Weinstein, Esq.
Printed Name

A copy of the letter authorizing Charles Weinstein, Esq., Executive Vice President and Chief Real Estate and Facility Officer, to sign for and act for the applicant for the project which is the subject of this application is included in Exhibit 8.

PART IV - CONSISTENCY WITH GENERAL REVIEW CRITERIA AT COMAR 10.24.01.08G(3):

INSTRUCTION: Each applicant must respond to all criteria included in COMAR 0.24.01.08G(3), listed below.

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

If a particular standard or criteria is covered in the response to a previous standard or criteria, the applicant may cite the specific location of those discussions in order to avoid duplication. When doing so, the applicant should ensure that the previous material directly pertains to the requirement and to the directions included in this application form. Incomplete responses to any requirement will result in an information request from Commission Staff to ensure adequacy of the response, which will prolong the application's review period.

10.24.01.08G(3)(a). <u>The State Health Plan</u>.

Every applicant must address each applicable standard in the chapter of the State Health Plan for Facilities and Services.[1] Commission staff can help guide applicants to the chapter(s) that applies to a particular proposal.

Please provide a direct, concise response explaining the project's consistency with each standard. Some standards require specific documentation (e.g., policies, certifications) which should be included within the application as an exhibit.

SURGERY Standards

10.24.11.05A. 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]Copies of all applicable State Health Plan chapters are available from the Commission and are available on the Commission's web site here:http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs_shp

Standard .05(A)(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.

Applicant Response

Children's will make information regarding charges for the full range of surgical services readily available to the public, upon inquiry, or as required by applicable regulations or laws. In an Ambulatory Surgical Facility, the gross charge structure is not always relevant to what patients (even private paying patients) may pay. Because Medicaid and private payors pay at different contracted rates, Children's will assist patients in determining what their estimated total charges and any applicable copays and deductibles will be.

Standard .05(A)(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:

(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.

(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.

(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.

(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.

(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

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

(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.

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

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

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

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

Applicant Response

(a) It is the policy of Children's to provide financial assistance to patients who are unable to pay their hospital and/or clinic bills due to difficult financial situations regardless of age, gender, race, creed, disability, social or immigrant status, sexual orientation, or religious affiliation, as codified in Children's Financial Assistance Policy (the "FAP"). The FAP, which will be the same FAP for the proposed ambulatory surgery facility, is provided in Exhibit 9, and incorporates the following elements mandated by COMAR 10.24.11.05(A)(2):

(i) **Determination of Eligibility for Charity Care:** As a specialty Children's Hospital, most of Children's uncovered patients qualify for a state Medicaid plan or for an income based safety plan such as Maryland Children's Medical Service. Children's has never used extraordinary collection efforts against patients and tends to be more generous in covering any child at 400% of the federal poverty level.

Children's understands the COMAR requirement to make a determination of probable eligibility for charity care within two business days following a patient's request for charity care services, application for medical assistance, or both. This requirement, while advantageous to patients of a typical acute care hospital, is not beneficial to Children's patients and families. Children's is unique in terms of patient care services; most of its patients are eligible for some form of coverage. Children's patient population is 55% Medicaid (crossing three state jurisdictions). Children's does not solely look at Medicaid and charity, but also Children's Medical Services, Medical Care for Children Partnership (MCCP), Bridge, Care for Kids, and other programs, to

ensure its patients have wrap around services to meet their healthcare needs in their community. In addition, Children's policy provides charitable coverage for patients up to 400% of the federal poverty guideline (FPL). In order to ensure the maximum amount of coverage for healthcare services, it is imperative that Children's allow families ample opportunity to obtain and provide the documentation needed, which often takes several days, if not longer, and to work with Children's on charity care eligibility as well as eligibility for other state and local safety net programs.

Children's will make reasonable efforts to make an initial determination of probable eligibility for charity care within two business days of a patient's request for charity care services, application for medical assistance, or both. Given the unique nature of Children's patient population, to address the COMAR requirement, the FAP states that Children's "will make Financial Assistance determination within two business days of receiving a completed application, including all required documentation."

Children's remains open to working with MHCC to ensure its FAP meets both MHCC's needs as well as the needs of the children served by Children's.

(ii) **Notice of Charity Care Policy:** As outlined in Section III (*Procedures: Communication of Financial Assistance to Patients and within the Community*) of the FAP, Children's makes information regarding financial assistance available through conspicuous postings in (amongst other locations) admitting and registration departments, hospital business offices, and patient financial services offices at all Children's facilities. Copies of the FAP are available in English and Spanish on Children's main website, www.childrensnational.org.

(iii) **Criteria for Eligibility:** As outlined in Section III (*Procedures: Basis for Determining Financial Assistance*) of the FAP, Children's does not bill patients whose family income is at or below 400% of the FPL and that have resided in the designated primary service area (as defined in the Service Area section of this application) for at least six months for any emergency or medically necessary care. The criteria for eligibility imposed by Children's are intended to provide charity care to a much larger proportion of the population than the criteria mandated by COMAR 10.24.11.05(A)(2).

(b) Section (b) is not applicable.

(c) Since its inception in 1870, Children's has generously delivered life-saving and innovative care to pediatric patients from all walks of life regardless of their ability to pay. Through the proposed project, Children's commits to expanding the regional impact of its charitable purpose to Prince George's County and the surrounding communities. In the proposed new ambulatory surgery facility, Children's will 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 financial projections for the proposed project include charity care amounting to 2.1% of operating expenses during the first year of operation, increasing to 2.7% of operating expenses by the third year of operation, far exceeding the current average amount of charity care provided by ASFs in the most recent year reported, 0.52%. An email from MHCC verifying this amount to be the current average amount of charity care provided by ASFs in the most recent year reported is provided in Exhibit 10.

(i) Children's has a track record of providing charitable health care facility services that meet or exceed the average amount of charity care provided by ASFs. Children's has provided charity care in the amount of 4.83% and 4.46% of operating expenses at its Montgomery County ASF over the most recent two years, far exceeding the average for all ASFs in those years.

(ii) As stated above, since its inception in 1870, Children's has generously delivered life-saving and innovative care to pediatric patients from all walks of life regardless of their ability to pay. Through the proposed project, Children's commits to expanding the regional impact of its charitable purpose to Prince George's County and the surrounding communities. Its track record in this regard speaks for itself, as does the Letter of Support submitted for the proposed project by Greater Baden Medical Services, Prince George's County's longest serving safety net health center.

(iii) Not applicable.

(d) Standard (d) is not applicable.

Standard .05(A)(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.

(b) A hospital shall document that it is accredited by the Joint Commission.

(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.

Applicant Response

Sub-sections (a) and (c) are not applicable to the proposed project.

(b) Children's principal inpatient facility, Children's Hospital, a subsidiary of Children's National Medical Center, located at 111 Michigan Avenue N.W. in the District of Columbia, is accredited by The Joint Commission (TJC). A copy of the TJC accreditation certificate, issued on July 23, 2016, is included in Exhibit 11.

(d) The proposed project will:

(i) Meet or exceed the minimum requirements for licensure by the State of Maryland Office of Health Care Quality, consistent with other Children's facilities (as demonstrated in Exhibit 12), including the following:

a. **Administration**: In compliance with COMAR 10.05.05.04 ("Administration"), Children's will appoint an administrator (the "Administrator") and a medical director (the "Medical Director") to develop protocols for the management of surgical patients

in emergency situations.

b. **Personnel**: In compliance with COMAR 10.05.05.05 ("Personnel"), the Administrator and Medical Director will be responsible for ensuring that the ASF is staffed by licensed and credentialed health care professionals, and for ensuring that all staff follow evidence-based practice standards and those prescribed by their respective professional organizations.

c. **Surgical Services Provision**: In compliance with COMAR 10.05.05.05.06 ("Surgical Services"), the Administrator and Medical Director will develop and implement policies, procedures, and protocols for the provision of surgical services.

d. **Anesthesia Services Provision**: In compliance with COMAR 10.05.05.05.07 ("Anesthesia Services"), the ASF will employ the services of qualified health practitioners (as determined by the Health Occupations Article of the Annotated Code of Maryland) for the provision of anesthesia services.

e. **Emergency Services Provision:** In compliance with COMAR 10.05.05.05.08 ("Emergency Services"), the ASF will make the necessary arrangements to ensure the availability of the necessary staff and equipment to appropriately respond to emergent situations.

f. **Hospitalization:** Information regarding the proposed project's compliance with COMAR 10.05.05.05.09 ("Emergency Services") is provided in the "Transfer Agreements" (Part IV - Standard 10.24.11.05(A)(4)) section of this application.

g. **Pharmaceutical Services:** In compliance with COMAR 10.05.05.05.10 ("Pharmaceutical Services"), the Administrator will develop and implement policies and procedures for pharmacy services and establish the necessary standards to ensure the appropriate administration of drugs.

h. **Laboratory and Radiologic Services:** In compliance with COMAR 10.05.05.05.11 ("Laboratory and Radiologic Services"), the Administrator will develop and implement policies and procedures for obtaining routine and emergency laboratory and radiologic services.

i. **Medical Records:** Medical records maintained by the ASF shall comply with the standards set forth by COMAR 10.05.01.09 ("Medical Records") and COMAR 10.05.05.05.12 ("Medical Records").

(ii) Children's will obtain accreditation of the ASF by The Joint Commission ("TJC") within two years of initiating services at the proposed project, consistent with other facilities owned/operated by Children's.

Standard .05(A)(4) Transfer Agreements.

(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.

Applicant Response

(a) As a highly specialized pediatric hospital, Children's will transfer any emergencies that may arise at the proposed new facility to Children's Hospital. Children's Hospital is the second closest hospital, 11.5 miles away from the PGC ROC location. Children's Hospital is fully staffed with specialized board certified pediatric experts in the care for children. It is uniquely situated with an emergency transport system through which Children's will deploy its ambulance to the site in case of an emergency. Since any such transfers will occur within the Children's system, a formal transfer agreement is not necessary.

However, if deemed necessary by MHCC, upon completion of the proposed project, Children's will enter into a written transfer agreement, consistent with the form presented in Exhibit 13, with another nearby acute care hospital.

(b) Pursuant to the guidelines set forth in Health-General Code Article §19-308.2, if deemed necessary, the transfer agreement between the ASF and another nearby acute care hospital will provide for the following recitals, all of which are outlined in Exhibit 13:

(i) "*Notification to the receiving hospital before the transfer and confirmation by that hospital that the patient meets that hospital's admissions criteria relating to appropriate bed, physician, and other services necessary to treat the patient;"*

(ii) *"The use of medically appropriate life-support measures that a reasonable and prudent physician exercising ordinary care would use to stabilize the patient before transfer and to sustain the patient during the transfer;"*

(iii) "*The provision of appropriate personnel and equipment that a reasonable and prudent physician exercising ordinary care would use for the transfer; and"*

(iv) *"The transfer of all necessary records for continuing the care for the patient."*

(c) Pursuant to the guidelines set forth in COMAR 10.05.05.09, the ASF will adhere to the existing emergency transfer protocol employed across all Children's facilities, a depiction of which is provided in Exhibit 14, and includes the following provisions:

(i) "*Having a written transfer agreement with a local Medicare participating hospital;"*

(ii) *"Having a mechanism for notifying the hospital of a pending emergency case;"*

(iii) *"Having a mechanism for arranging appropriate transportation to the hospital; and"*

(iv) *"The manner in which a facility sends a copy of the patient's medical record to the hospital."*

10.24.11.05B. Project Review Standards.

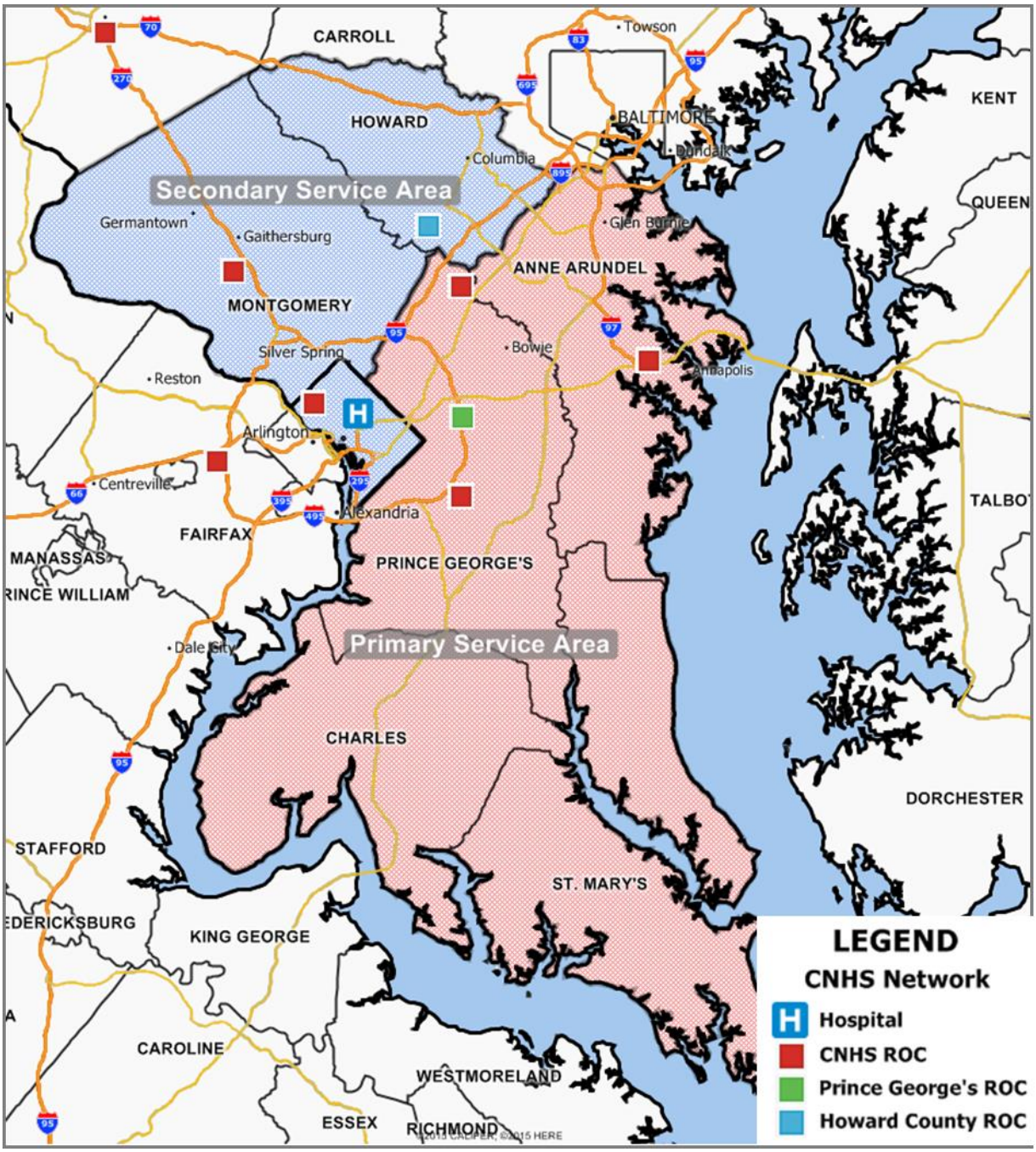
The standards in this section govern reviews of Certificate of Need applications and requests for exemption from Certificate of Need review involving surgical facilities and services. An applicant for a Certificate of Need or an exemption from Certificate of Need shall demonstrate consistency with all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

Standard .05B(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.

Applicant Response

As a specialized pediatric ambulatory surgery facility, the proposed new ASF will draw patients from a wider area than a typical adult-oriented ASF. Based on its experience at its other ASFs and the limited availability of other specialized pediatric ambulatory surgical services in eastern and southern portions of central Maryland, Children's has identified the areas depicted on the map below to be the primary and secondary service areas for the proposed facility. Specifically. The primary service area includes Prince George's, Charles, Anne Arundel, St. Mary's, and Calvert Counties in Maryland. The secondary service area includes Montgomery and Howard Counties in Maryland and the District of Columbia. A map of the primary and service areas is provided below. A list of ZIP Codes included in the primary and secondary service areas is provided in Exhibit 15.


CARROLL
HOWARD
Towson
BALTIMORE
Dundalk
KENT
QUEEN
Columbia
Secondary Service Area
Germantown
Gaithersburg
Glen Burnie
ANNE ARUNDEL
MONTGOMERY
Silver Spring
Bowie
Annapolis
Reston
Arlington
Centreville
Alexandria
FAIRFAX
MANASSAS
PRINCE GEORGE'S
Primary Service Area
Dale City
CHARLES
DORCHESTER
STAFFORD
ST. MARY'S
KING GEORGE
CAROLINE
WESTMORELAND
ESSEX
RICHMOND
LEGEND
CNHS Network
Hospital
CNHS ROC
Prince George's ROC
Howard County ROC

Standard .05B(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:

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

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

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

(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.

Applicant Response

Standard .05(B)(2)(a) is not applicable to the proposed project.

Background

Children's has a longstanding history of, and commitment to, providing high-quality, specialized pediatric care across the region. Over time, the organization has expanded from its main campus in Washington, D.C. to offer multiple regional outpatient centers to better meet the needs of the communities in which they are developed.

The proposed project aligns with the evolution of Children's services by offering specialized surgical services to a population without appropriate, convenient access to these services today. Currently, a significant portion of pediatric patients receiving ambulatory surgical care at the main campus reside in

the proposed service area and must travel significant distances and navigate the notorious Washington, DC area traffic for outpatient care. Offering these services in the community where patients live is critical to ensuring equitable access to these services, particularly for vulnerable and low-income populations. Further, appropriately shifting this care back into the community will increase capacity at the main campus to support more complex cases, anticipated future growth in demand from the District and neighboring Northern Virginia, and the continuing shift in care from the inpatient to the outpatient setting.

The need for the proposed project was determined through analysis of service area population characteristics and growth trends, forecasted trends in pediatric ambulatory surgical demand, trends in Children's ambulatory surgery cases from the primary service area, patient origin of ambulatory surgical cases currently being performed by physicians who will practice in the PGC ROC, and Children's expected capacity at the new facility. The analysis, presented below, demonstrates the need for the proposed project.

Service Area and Demographic Trends

As described in the response to Standard .05B(1) Service Area (above), the proposed project's primary service area is defined as Prince George's, Anne Arundel, Calvert, Charles and St. Mary's Counties, and the secondary service area includes the District of Columbia, Montgomery County, and Howard County.

Population estimates for these counties and the District of Columbia were obtained from demographic data prepared by Claritas, Inc. Pursuant to COMAR 10.24.11.06E, an applicant may utilize population data other than those supplied by the Maryland Department of Planning or the U.S. Bureau of the Census if that applicant demonstrates the reasonableness and reliability of such a data source. Based upon the following considerations, Children's elected to utilize such an alternative data source:

- Population estimates developed by the Maryland Department of Planning do not include the District of Columbia, a core geographic region included in the proposed project's secondary service area;
- Children's analysis of need relied upon market estimate data supplied by Truven Health Analytics, Inc., which is widely regarded as the authoritative source for health planning data and which utilizes population estimates developed by Claritas, Inc.;
- The Maryland Health Care Commission has previously approved CON applications in which the demonstrated need was validated using population estimates developed by Claritas, Inc[2].; and
- Claritas, Inc. employs historical data developed by the U.S. Bureau of the Census, one of the two recognized data sources enumerated in COMAR 10.24.11.06 (E).

Based upon the factors outlined above, Children's submits the population estimates developed by Claritas, Inc. and supplied by Truven Health Analytics, Inc. as reasonable and reliable for the purposes of this analysis. These estimates for the counties encompassing the primary and secondary service areas are provided in the table below.

[2] In the matter of Sheppard Pratt at Elkridge (Docket No. 15-13-2367) before the Maryland Health Care Commission, the application approved on September 20, 2016 relied upon population estimates whose source was Claritas, Inc.

Service Area Population Estimates, 2017 to 2022 (0 to 17 Years Old)[1]				
	CY 2017	CY 2022	Population Change	% Change
Primary Service Area				
Prince George's County	206,860	213,461	6,601	3.2%
Anne Arundel County	125,438	128,789	3,351	2.7%
Calvert County	21,161	19,870	(1,291)	-6.1%
Charles County	37,655	36,646	(1,009)	-2.7%
St. Mary's County	27,222	27,667	445	1.6%
Total Primary Service Area	**418,336**	**426,433**	**8,097**	**1.9%**
Secondary Service Area				
District of Columbia	128,397	144,783	16,386	12.8%
Montgomery County	248,340	255,963	7,623	3.1%
Howard County	74,746	74,083	-663	-0.9%
Total Secondary Service Area	**451,483**	**474,829**	**23,346**	**5.2%**
Combined Service Area	**869,819**	**901,262**	**31,443**	**3.6%**

[1]Source: Claritas,Inc. Data obtained from Truven Health Analytics, Inc.

In assessing the data shown above, Children's observed the following trends:

- Overall estimated pediatric population growth in the service area of 3.6%; including growth of 1.9% in the Primary Service Area and 5.2% in the secondary service area; and
- Notable primary service area pediatric growth in Prince George's and Anne Arundel Counties of 3.2% and 2.7%, respectively.

In addition to evaluating growth in the pediatric population, Children's considered the overall socioeconomic and demographic characteristics of the population in the primary and secondary service areas, as summarized in Exhibit 16.

The growth in the pediatric population in the service area and in Prince George's County, in particular, supports an increasing need for services specifically geared toward the pediatric population in the future. The demographic characteristics reinforce the essential nature of a provider like Children's and its commitment to serve all segments of the population.

Historical Trends in Utilization of Ambulatory Surgical Services

As summarized in the table below, ambulatory surgery volumes in ambulatory surgery facilities in the primary service area increased by 31.2% between 2011 and 2015, as reported by the Maryland Health Care Commission's public use data for all ASFs.

Primary Service Area Ambulatory Surgery Facility Utilization, 2011 - 2015[1]					
	Total OR Cases				
	CY 2011	CY 2012	CY 2013	CY 2014	CY 2015
Primary Service Area					
Prince George's County	10,706	12,616	16,465	19,168	20,527
Anne Arundel County	20,329	20,946	21,325	24,751	23,051
Calvert County	1,525	1,794	1,776	1,795	1,791
Charles County	3,261	2,399	2,577	828	487
St. Mary's County	540	1,706	1,916	1,841	1,858
Total Primary Service Area	36,361	39,461	44,059	48,383	47,714
% Growth (Year-to-Year)	*N/A*	*8.5%*	*11.7%*	*9.8%*	*-1.4%*
% Growth (Period)					*31.2%*

[1]Source: State of Maryland, Health Care Comission Public Use Data (as of December 1, 2017).

In reviewing ASF utilization in the primary service area, Children's observed the following trends:

- ASF utilization in Prince George's County increased by 91.7% between 2011 and 2015, with an average increase of approximately 23% per year over that period; and
- Despite county-level variation across the period, ASF utilization in the primary service area increased by an average of approximately 8% annually between 2011 and 2015.

Although the demand for ambulatory surgical services has grown significantly for patients of all ages in the primary service area, Children's considers the demand for services specific to pediatric patients (as discussed in the section that follows) to be a more reliable indicator of the need for the proposed project.

Anticipated Growth in Utilization of Pediatric Ambulatory Surgical Services

A variety of factors contribute to the growth in pediatric ambulatory surgical services in the market. Population growth (described above) is a significant driver as is the continued shift of services nationally from an inpatient to an outpatient environment. This shift in care settings can be attributed to technology and medical advances, lower cost for comparable outcomes, and patient preference for convenient alternatives to inpatient care, among others.

Utilization trends in the primary service area of the proposed project are expected to be consistent with these national trends, resulting in significant forecasted growth in pediatric outpatient surgical procedures.

Children's obtained outpatient demand estimates for pediatric surgery from Truven Health Analytics, Inc., a nationally recognized source of market demand forecast data and outpatient demand estimates for pediatric surgical[3] cases. These data, by county and in total for the proposed primary service area, by specialty, are provided in the table below.

Estimated Primary Service Area Outpatient Surgical Procedures (0-17 years old), by Specialty[1]

	Prince George's			Anne Arundel			Calvert			Charles			St. Mary's			Total - All Counties		
	Cur.	5 Yr.	10 Yr.	Cur.	5 Yr.	10 Yr.	Cur.	5 Yr.	10 Yr.	Cur.	5 Yr.	10 Yr.	Cur.	5 Yr.	10 Yr.	Cur.	5 Yr	10 Yr
Ambulatory Surgical Procedures																		
Otolaryngology	2,430	2,632	2,794	1,856	2,001	2,121	255	251	248	459	468	475	308	329	347	5,308	5,681	5,985
Orthopedics	477	533	586	515	558	603	111	109	109	95	99	104	50	55	61	1,248	1,354	1,463
Urology	147	154	160	194	205	215	24	23	22	26	25	25	14	14	15	405	421	437
General Surgery	87	107	113	76	93	98	9	10	9	16	19	20	9	10	10	197	239	250
Gastroenterology	198	210	219	142	150	156	19	18	18	63	63	63	53	55	57	475	496	513
Ophthalmology	144	152	158	91	96	99	16	15	14	27	27	26	19	20	20	297	310	317
Oral Surgery	154	178	195	94	108	118	16	17	17	28	31	32	20	23	25	312	357	387
Dermatology	33	35	37	166	176	183	33	32	31	9	9	9	33	34	35	274	286	295
Plastic Surgery	21	23	24	26	28	30	5	5	5	4	4	4	4	4	4	60	64	67
Podiatry	35	36	37	29	29	30	2	2	1	3	3	3	1	1	1	70	71	72
Pain Management	58	60	60	53	55	56	8	8	7	25	24	24	10	11	11	154	158	158
Other	27	30	31	12	14	14	2	2	2	3	3	3	2	2	3	46	51	53
Total Ambulatory Surgery Procedures	**3,811**	**4,150**	**4,414**	**3,254**	**3,513**	**3,723**	**500**	**492**	**483**	**758**	**775**	**788**	**523**	**558**	**589**	**8,846**	**9,488**	**9,997**
% Growth (from Current Year)	*N/A*	*8.9%*	*15.8%*	*N/A*	*8.0%*	*14.4%*	*N/A*	*-1.6%*	*-3.4%*	*N/A*	*2.2%*	*4.0%*	*N/A*	*6.7%*	*12.6%*	*N/A*	*7.3%*	*13.0%*
Hospital Outpatient Surgical Procedures																		
Otolaryngology	4,052	4,087	4,092	2,518	2,527	2,527	425	390	364	750	712	681	531	528	526	8,276	8,244	8,190
Orthopedics	1,582	1,508	1,482	1,135	1,073	1,046	170	150	138	360	321	298	207	197	195	3,454	3,249	3,159
Urology	909	930	951	600	613	626	93	87	83	158	152	148	121	123	125	1,881	1,905	1,933
General Surgery	902	964	1,018	566	601	632	88	86	84	172	173	175	121	128	134	1,849	1,952	2,043
Gastroenterology	462	473	483	284	290	296	101	94	90	69	67	65	57	57	58	973	981	992
Ophthalmology	369	380	390	227	232	237	39	36	34	69	67	66	52	53	54	756	768	781
Oral Surgery	317	349	373	199	219	233	33	34	33	59	61	62	42	46	49	650	709	750
Dermatology	178	173	171	127	122	121	18	16	15	38	35	33	25	24	24	386	370	364
Plastic Surgery	149	152	156	98	100	102	11	10	10	28	27	27	30	30	31	316	319	326
Podiatry	86	88	90	75	76	77	7	6	6	21	20	20	11	11	11	200	201	204
Pain Management	42	43	44	35	36	37	18	17	16	5	5	5	13	13	14	113	114	116
Other	227	242	256	148	155	164	23	22	23	55	56	55	35	37	39	488	512	537
Total Hospital Outpatient Surgical Procedures	**9,275**	**9,389**	**9,506**	**6,012**	**6,044**	**6,098**	**1,026**	**948**	**896**	**1,784**	**1,696**	**1,635**	**1,245**	**1,247**	**1,260**	**19,342**	**19,324**	**19,395**
% Growth (from Current Year)	*N/A*	*1.2%*	*2.5%*	*N/A*	*0.5%*	*1.4%*	*N/A*	*-7.6%*	*-12.7%*	*N/A*	*-4.9%*	*-8.4%*	*N/A*	*0.2%*	*1.2%*	*N/A*	*-0.1%*	*0.3%*

[1]Source: Truven Health Analytics, Inc. 2017.

As shown in the table above, pediatric ambulatory surgery procedures performed in an ambulatory

[3] Truven Health Analytics, Inc.; Patient ages 0-17.

surgery center (as opposed to a hospital outpatient setting) are expected to increase 7.3% over the next 5 years and 13.0% over the next 10 years in the primary service area, with the most significant growth, 8.9% and 15.8%, respectively, expected to occur in Prince George's County, the location of the proposed project. Additional key findings from the data include the following:

- Total pediatric ambulatory surgery procedures performed in freestanding ambulatory surgery centers in the primary service area is forecast to increase by approximately 1,150 procedures over the next ten years. Based on Children's experience of about 1.6 procedures per pediatric ambulatory surgery case, the primary service area is estimated to experience an increase of about 720 pediatric cases in freestanding ambulatory surgery settings over that period.
- As noted above, of the five-county primary service area, Prince George's County (where the proposed project is located) is driving the growth in demand in pediatric ambulatory surgery in the service area. Total pediatric ambulatory surgery procedures performed in freestanding ambulatory surgery centers in Prince George's County is forecast to increase by more than 600 procedures over the next ten years, for an estimated increase of 375 pediatric cases in freestanding ambulatory surgery settings over that period.
- While total Hospital Outpatient procedure volume in the primary service area is forecast to remain relatively flat over the next ten years, there is considerable variation at the county level, with Prince George's County forecast to experience a 2.5% increase in Hospital Outpatient procedures over that period, representing approximately 230 procedures or 145 cases.

Historical reported information on outpatient surgery volumes for the market do not specifically track pediatric outpatient surgery as a separate category, although the MHCC does report surgeries by age, including for the 0-14 age group, but only by site of service rather than patient origin. However, Children's internal data is consistent with the trends identified above and show an increase in ambulatory surgical cases from patients residing in both the primary and secondary service areas. As shown in the table below, pediatric ambulatory surgical cases from the primary service area grew 4% over the previous fiscal year, while the secondary service area experienced a volume growth of 10%.

Same Day Surgical Cases, Main Hospital[1]						
	FY 2016		FY 2017		Change	
	Cases	% of Total	Cases	% of Total	Cases	%
Primary Service Area						
Prince George's County	2,249	24.2%	2,334	23.7%	85	3.8%
Anne Arundel County	428	4.6%	425	4.3%	-3	-0.7%
Calvert County	184	2.0%	208	2.1%	24	13.0%
Charles County	195	2.1%	212	2.2%	17	8.7%
St. Mary's County	157	1.7%	162	1.6%	5	3.2%
Total Primary Service Area	3,213	34.6%	3,341	33.9%	128	4.0%
Secondary Service Area						
District of Columbia	1,994	21.5%	2,194	22.3%	200	10.0%
Montgomery County	1,536	16.5%	1,695	17.2%	159	10.4%
Howard County	85	0.9%	88	0.9%	3	3.5%
Total Secondary Service Area	3,615	38.9%	3,977	40.4%	362	10.0%
Combined Service Area	6,828	73.5%	7,318	74.4%	490	7.2%
Total Same Day Surgical Cases	9,289	100%	9,841	100%	552	5.9%

[1]Source: Children's National Medical Center, 2017.

Projected Volumes

As indicated previously, the proposed new ambulatory surgery facility will be located in the new PGC ROC, which will house a wide range of pediatric sub-specialists, including physicians who currently practice at the two existing outpatient centers located in Prince George's County, as well as new physicians to be recruited by Children's. Pediatric surgical sub-specialties to be offered at the PGC ROC include ENT, General Surgery, Gastroenterology, Ophthalmology, Plastic Surgery, Urology, and Orthopedics.

The existing surgeons who will be relocated to the PGC ROC currently perform most of their surgical cases at the main Children's campus. Traveling all the way from Prince George's County and the surrounding counties in Maryland to Children's main campus in the District of Columbia for outpatient surgical services is sub-optimal for care and recovery of pediatric patients and poses an unnecessary hardship on patients and their families. The new ASF will be highly attractive to these physicians, their patients, and their patients' families, and will make care more accessible and convenient to the service area population in need of such services.

Initial planned surgical volumes will primarily be driven by a shift of patients from the Children's outpatient surgical unit at the main hospital in Washington D.C. As shown in the table above, currently, approximately 58% of the surgeries at the main hospital location are performed on patients who reside in Maryland, and 34% are performed on patients from the proposed primary service area for the proposed ASF. Shifting a portion of these cases to this new ASF is not only convenient for patients, it also allows Children's to free up capacity in the hospital operating rooms for more complex surgical cases that require additional specialty back-up and/or inpatient care.

Additionally, Children's anticipates substantial growth in surgical cases for patients residing closer to the main hospital campus, both in Washington, D.C. proper and in northern Virginia. Shifting a portion of the current surgical volume to the new ASF, closer to where the patients and their families live, will allow Children's to accommodate the expected growth in volume at the main hospital campus.

Children's identified the pediatric surgeons who are expected to be relocated to and practice in the PGC ROC. In consultation with physician leaders, volume was estimated by physician through analysis of each physician's current volume of cases performed on patients from the primary service area and discussion about, based on a conservative estimate, what proportion of those cases would likely be performed at the new facility once the new ambulatory surgery facility opens. For example, in FY17, Dr. Alexandra Espinel performed 530 ambulatory surgery cases at the main campus, 220 of which were on patients who reside in the primary service area. Children's estimated that approximately half of that volume could be captured in year one of the proposed facility, with that volume increasing slightly each year thereafter.

Children's is also planning to recruit or is already in the process of recruiting new pediatric surgeons who will also practice in the PGC ROC. Volumes were estimated for these new physicians as well based on expected future growth in demand in the primary service area. Additionally, volume estimates are shown for community physicians who are currently in private practice within the service area, have privileges at Children's, and either bring patients to the surgery center on the main campus, or those not currently affiliated with any surgery center.

As indicated above, future growth in surgical cases at the proposed ASF is expected to be driven by pediatric population growth in the service area, the continued shift of cases from the inpatient to the outpatient setting, and some movement of pediatric surgical cases currently being performed in freestanding ASF's designed for and primarily serving adults to this more appropriate, highly specialized, pediatric surgery center.

Estimated volume, by physician and specialty, is summarized in the table below.

Estimated Surgical Cases, by Physician and Specialty[1]					
Specialty	**Physician**	**Year 1**	**Year 2**	**Year 3**	**Year 4**
ENT	Dr. Alexandra Espinel	121	128	140	140
	Dr. Pamela Mudd	107	112	130	130
	Dr. Maria Pena	119	123	125	133
	Dr. Diego Preciado	73	73	125	125
	Physician(s) to be recruited	-	85	280	280
	Total - ENT	**420**	**521**	**800**	**808**
General Surgery	Dr. Mikael Petrosyan	334	344	385	389
	Physician(s) to be recruited	-	-	303	306
	Total - General Surgery	**334**	**344**	**688**	**695**
Gastroenterology	Dr. Sravan Matta	84	86	172	173
	Total - Gastroenterology	**84**	**86**	**172**	**173**
Hematology/Oncology	Dr. Evelio Perez	25	26	52	53
	Total - Hematology/Onc.	**25**	**26**	**52**	**53**
Ophthalmology	Dr. Marlet Bazemore	38	39	40	41
	Dr. Heather deBeaufort	39	40	42	42
	Total - Ophthalmology	**77**	**79**	**82**	**83**
Orthopedic Surgery	Dr. Emily Niu	30	31	32	32
	Physician(s) to be recruited	-	-	50	51
	Total - Orthopedic Surgery	**30**	**31**	**82**	**83**
Plastic Surgery	Dr. Gary Rogers	84	100	120	121
	Total - Plastic Surgery	**84**	**100**	**120**	**121**
Urology	Dr. Nadia Kalloo	117	122	137	138
	Physician(s) to be recruited	62	62	128	129
	Total - Urology	**179**	**184**	**265**	**267**
Other Specialties (Dentistry, Physical Medicine & Rehabilitation)	Dr. Sally Evans	58	60	139	140
	Total - Other Specialties	**58**	**60**	**139**	**140**
Community Physicians	Community Physicians	-	-	155	157
	Total - Community Physicians	**-**	**-**	**155**	**157**
Total Cases		**1,291**	**1,430**	**2,555**	**2,579**

[1]Source: Developed by Children's National Medical Center, 2017.

Projected Capacity

By its specialized nature, pediatric care and, specifically, pediatric ambulatory surgery, is unique. It requires specially equipped rooms, pediatric trained staff members and physicians, and an operating model that is different than an adult model.

To the best of Children's knowledge and belief, there is currently no applicable State Health Plan need analysis specifically applicable to pediatric outpatient surgery. Therefore, Children's calculates its capacity based on its own experience as a premier provider of pediatric services and the differences in operating model required to meet the needs of pediatric patients. This calculation is described below:

Current Maryland State Health Plan ASF 'optimal capacity' assumptions:

1. Operating rooms are available 255 days per year, 8 hours per day; and
2. Full capacity of 2,040 hours per year and optimal capacity of 80%, or 1,632 hours

Children's actual experience at its other ASFs is as follows:

1. Operating rooms available 251 weekdays per year (closed 9 weekdays each year).
2. Open 8.5 hours each day, between hours of 7 a.m. - 3:30 pm, with 7 hours of surgical time (first case start at 7:30 a.m. with last case at 2:30 p.m.).

3. Average time per case is 65 minutes (based on average of 40 surgical minutes per case and turnover time of 25 minutes per case) in years 1 and 2 of operation.
4. Average time per case at the proposed facility will be 67 minutes (based on average of 42 surgical minutes per case and turnover time of 25 minutes per case) in years 3 and 4 of operation due to the following:
    a. Volume of community dental and oral surgery cases with more than double the average case length of other types of cases; and
    b. Increase in orthopedic sports cases with longer average case time.

Therefore, Children's anticipates its optimal capacity to be 1,291 cases per operating room in per year in years 1 and 2 of operation, or 80% of 1,622 cases per operating room per year at maximum capacity; and 1,258 cases per operating room in per year in years 3 and 4 of operation, or 80% of 1,573 cases per operating room per year at maximum capacity. The volume projections for the proposed project (as provided in Table 2 under 10.24.01.08G(3)(b). Need) demonstrate that the proposed two OR facility will achieve optimal capacity by the third year of operation.

Standard .05B(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 .06 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. The needs assessment shall include the following:

(i) Historic trends in the use of surgical facilities at the existing facility;

(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.

Applicant Response:

Standard 10.24.11.05(B)(3) does not apply to the proposed project.

Standard .05B(4) Design Requirements.

Floor plans submitted by an applicant must be consistent with the current FGI Guidelines.

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

(b) An ASF shall meet the requirements in 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.

Applicant Response

Sections (a) and (c) do not apply to the Proposed Facility.

(b) A certification of the proposed facility's compliance with Section 3.7 of the FGI Guidelines, issued by the principal architect of the proposed facility (a member in good standing of the American Institute of Architects), is included in Exhibit 17.

Standard .05B(5) Support Services.

Each applicant shall agree to provide as needed, either directly or through contractual agreements, laboratory, radiology, and pathology services.

Applicant Response

The ROC in which the proposed facility will be located includes on-site phlebotomy, laboratory, and transfusion services.

Advanced laboratory testing and pathology services will be available via courier to the main Children's campus in Washington, D.C. (approximately 10 miles from the PGC ROC).

The PGC ROC will include an imaging center, which will include, at a minimum, diagnostic x-ray, ultrasound, and fluoroscopy.

All support services will be rendered directly by Children's-employed providers.

Standard .05B(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.

Applicant Response

(a) As one of the nation's top performing children's hospitals for patient safety (as ranked by the Leapfrog Group's Top Hospitals program), patient safety plays a critical role in every decision made by Children's leadership. The planning process for the proposed project sought and incorporated input from various internal and external stakeholders, including patient safety, risk management, facility design, and care delivery champions. In planning for the proposed project, Children's sought to achieve the following patient safety-related objectives:

(iv) Maximize privacy and comfort for patients and families;

(v) Maintain effective infection prevention and control barriers;

(vi) Reduce opportunities for medical error; and

(vii) Minimize staff response time in the event of an emergency.

(b) Children's commitment to providing the safest possible care for the diverse pediatric patient population that will be served by the proposed project is evident throughout the design of the facility, which includes the following elements:

(i) **Private Prep/Recovery Rooms:** Each Prep and Recovery Room has been designed as a private room with glass ICU sliding doors with a break-away feature. Private rooms enhance patient privacy and reduce public access to the patient, which improves the patient experience while allowing caregivers visual access to the patient and quick removal of the patient from the room in the event of an emergency.

(ii) **Private Prep/Recovery Rooms Sinks:** Each Prep and Recovery Room has been designed as a private room with a sink. Having a sink for each patient station improves infection control by providing caregivers and patient family members direct access to handwashing facilities and reduces the risk of Ambulatory Surgery Center acquired infections.

(iii) **Acoustic Control:** All gypsum board on interior walls will run to the bottom of the slab above. This design feature will limit the transfer of noise between patient rooms, supporting patient well-being and privacy as well as enhancing communication among staff. It also improves safety, health, healing, and well-being by reducing medical errors as it supports open conversations among patients, families, and practitioners.

(iv) **FGI Guidelines:** Implementing the 2014 FGI Guidelines for Design of Construction of Hospitals and Outpatient Facilities and using inherently antimicrobial surfaces where appropriate will limit Ambulatory Surgery Center acquired infections and improve patient safety and quality.

(v) **Same-Handed Operating Rooms:** Same-handed operating rooms standardize equipment and supply locations to improve staff efficiency during surgical procedures and lessens the opportunity for errors.

Standard .05B(7) Construction Costs.

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

(a) Hospital projects.

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

(ii) If the projected cost per square foot exceeds the Marshall Valuation Service® benchmark cost, any rate increase proposed by the hospital related to the capital cost of the project shall not include:

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

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

(b) Ambulatory Surgical Facilities.

(i) The projected cost per square foot of 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.

Applicant Response

Standard (a) is not applicable to the proposed project.

Standard (b): As demonstrated below, the projected cost per square foot of the proposed project is below the Marshall & Swift Valuation Service (MSVS) benchmark for outpatient surgical centers.

A. Marshall & Swift Valuation Service Benchmark *1. Benchmark Information*	
Construction Type	Outpatient Surgical Centers
Construction Class	A
Stories in Building	3
Stories in Section	1
Perimeter	492
Height of Ceiling	16.6
Square Feet	10,700
2. Benchmark Basic Structure Costs (Per Square Foot)	
Base Cost	$ 351.69
Adjustment: Exterior Walls	$ 38.66
Adjustment: Heating & Cooling	$ 46.72
Adjustment: Sprinklers	$ 4.50
Total Benchmark Basic Structure Cost	$ 441.57
B. Proposed Project Capital Costs *1. New Construction Costs (Per Square Foot)*	
Building	$ 300.00
Fixed Equipment	$ 80.00
Site Preparation	$ 0.00
Architect/Engineering Fees	$ 23.00
Permits	$ 3.00
Total New Construction Costs	$ 406.00
2. Other Capital Costs	
Contingency Allowance	$ 30.45
3. Total Proposed Project Capital Costs	
Total Proposed Project Capital Costs	$ 436.45
C. Summary *1. Proposed Project Capital Costs Comparison to Benchmarks*	
Total Benchmark Basic Structure Cost	$ 441.57
Total Proposed Project Capital Costs	$ 436.45
Difference	$ (5.12)

Detailed benchmarks obtained from Marshall & Swift Valuation Service are included in Exhibit 18.

Standard .05B(8) Financial Feasibility.

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

(a) An applicant shall document that:

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

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

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

(iv) The 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.

Applicant Response

The proposed project is financially feasible, as shown in Table 4.

Utilization projections for the proposed project were determined through analysis of service area population characteristics and growth trends, forecasted trends in pediatric ambulatory surgical demand, trends in Children's ambulatory surgery cases from the primary service area, patient origin of ambulatory surgical cases currently being performed by physicians who will practice in the PGC ROC, and Children's expected capacity at the new facility. Accordingly, the utilization projections are consistent with observed historic trends in use of the applicable service(s) by the likely service area population of the facility.

Revenue estimates are consistent with the utilization projections and are based on current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity care provision, as experienced at Children's Montgomery County ASF. The charity care percentage is based on Children's experience at its Montgomery County ASC with consideration given to the statewide average of charity care provided by ASFs.

Staffing and overall expense projections are consistent with the utilization projections and are based on current expenditure levels and reasonably anticipated future staffing levels as experienced at Children's Montgomery County ASF.

As shown in Table 4, 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 3 years of initiating operations.

The list of assumptions that were used to develop the financial projections are provided in response to Standard 10.24.01.08G(3)(d), Viability of the Proposal.

Standard .05B(9) Preference in Comparative Reviews.

In the case of a comparative review of CON applications to establish an ambulatory surgical facility or provide surgical services, preference will be given to a project that commits to serve a larger proportion of charity care and Medicaid patients. Applicants' commitment to provide charity care will be evaluated based on their past record of providing such care and their proposed outreach strategies for meeting their projected levels of charity care.

Applicant Response

Standard .05B(9) is not directly applicable to the proposed project.

However, as a specialized pediatric ambulatory surgery facility, Children's anticipates that the payer mix at the new facility will serve a patient base composed of approximately 47% Medicaid, a substantially higher percentage than at other ambulatory surgery facilities in the primary service area.

10.24.01.08G(3)(b). Need.

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

INSTRUCTIONS: Please discuss the need of the population served or to be served by the Project.

Responses should include a quantitative analysis that, at a minimum, describes the Project's expected service area, population size, characteristics, and projected growth. If the relevant chapter of the State Health Plan includes a need standard or need projection methodology, please reference/address it in your response. For applications proposing to address the need of special population groups, please specifically identify those populations that are underserved and describe how this Project will address their needs.

If the project involves modernization of an existing facility through renovation and/or expansion, provide a detailed explanation of why such modernization is needed by the service area population. Identify and discuss relevant building or life safety code issues, age of physical plant issues, or standard of care issues that support the need for the proposed modernization.

Please assure that all sources of information used in the need analysis are identified. List all assumptions made in the need analysis regarding demand for services, utilization rate(s), and the relevant population, and provide information supporting the validity of the assumptions.

Complete Tables 1 and/or 2 below, as applies.

[(INSTRUCTION: Complete Table 1 for the Entire Facility, including the proposed project, and Table 2 for the proposed project only using the space provided on the following pages. Only existing facility applicants should complete Table 1. All Applicants should complete Table 2. Please indicate on the Table if the reporting period is Calendar Year (CY) or Fiscal Year (FY)]

Applicant Response

A detailed discussion and analysis of the need for the proposed project, including a quantitative analysis that describes the project's expected service area, population size, characteristics, and projected growth, as well as other factors, is provided in response to Standards .05B(1) Service Area and .05B(2) Need - Minimum Utilization for Establishment of a New or Replacement Facility.

Table 2 is shown below.

TABLE 2: STATISTICAL PROJECTIONS - PROPOSED PROJECT

	Projected Years (Ending with first full year at full utilization)[1]			
CY or FY (Circle)	CY2020	CY2021	CY2022	CY2023
Ambulatory Surgical Facilities				
a. Number of operating rooms (ORs)	2	2	2	2
● Total Procedures in ORs	2,065	2,280	4,088	4,126
● Total Cases in ORs	1,291	1,430	2,555	2,579
● Total Surgical Minutes in ORs*	51,880	57,226	107,310	108,338
b. Number of Procedure Rooms (PRs)	0	0	0	0
● Total Procedures in PRs	0	0	0	0
● Total Cases in PRs	N/A	N/A	N/A	N/A
● Total Minutes in PRs*	N/A	N/A	N/A	N/A

*Do not include turnover time

[1]Children's will achieve full utilization of the proposed project in CY2022, the third year of operation

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

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

INSTRUCTIONS: Please describe the planning process that was used to develop the proposed project. This should include a full explanation of the primary goals or objectives of the project or the problem(s) being addressed by the project. It should also identify the alternative approaches to achieving those goals or objectives or solving those problem(s) that were considered during the project planning process, including the alternative of the services being provided by existing facilities.

For all alternative approaches, provide information on the level of effectiveness in goal or objective achievement or problem resolution that each alternative would be likely to achieve and the costs of each alternative. The cost analysis should go beyond development cost to consider life cycle costs of project alternatives. This narrative should clearly convey the analytical findings and reasoning that supported the project choices made. It should demonstrate why the proposed project provides the most effective goal and objective achievement or the most effective solution to the identified problem(s) for the level of cost required to implement the project, when compared to the effectiveness and cost of alternatives including the alternative of providing the service through alternative existing facilities, or through an alternative facility that has submitted a competitive application as part of a comparative review.

Applicant Response

Planning and development for the proposed project reflects Children's commitment to furthering its mission of "providing a quality health care experience for our patients and families." Key components of this experience that were addressed through the goals of the proposed project include the following:

- 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.

As described in the Project Description and Standard .05B(2) - Need, an overall lack of pediatric subspecialty care coupled with the growing demand for pediatric ambulatory surgery in the service area drove the development of a comprehensive medical office building proposed to include two operating rooms.

Children's considered a variety of alternatives to the proposed project, as discussed in the sections that follow.

Do Nothing

Children's leadership evaluated the possibility of utilizing the substantial space dedicated to the proposed facility within the medical office building for other purposes, effectively "doing nothing" to enhance patient

access to pediatric ambulatory surgical services in Prince George's and surrounding counties. Adopting this approach, however, would be inconsistent with the goals of the proposed project established by Children's. As previously stated, the proposed new specialty pediatric ASF will offer the physicians to be housed in the PGC ROC, their patients and their families, a more convenient setting for care. The existing surgeons who will be relocated to the PGC ROC currently perform most of their surgical cases at the main Children's campus. Traveling all the way from Prince George's and the surrounding Counties in Maryland to Children's main campus in the District of Columbia for outpatient surgical services is sub-optimal for care and recovery of pediatric patients and poses an unnecessary hardship on patients and their families. The availability of a two-operating room ASF in the PGC ROC will make care more accessible and convenient to the service area population in need of such services. Accordingly, maintaining the status quo is not a viable option.

Build Freestanding Ambulatory Surgery Center

A standalone pediatric ambulatory surgical facility could be constructed in multiple locations in the region for a similar cost. However, co-locating the ambulatory surgical services with other components of the medical office building, including physician offices and amenities such as convenient parking, serve to enhance the care experience for patients and families and provide a much more collaborative and convenient setting for the physicians. Separating these services would not meet the stated goals of providing convenient and accessible care for patients.

Build PGC ROC at Another Location

Children's explored several other sites for development of the PGC ROC. Those sites and the reasons they were rejected as viable options are identified below.

Site	Location	Size	Comments
Fairwood Green	Bowie, MD	49,798 SF on 3 floors	Building was designed to be a business office building, making it to difficult and costly to retrofit for medical use
8401 Corporate Drive	Landover, MD	53,062 SF on 4 floors	Building was very dated and elevators would not meet requirements for medical use/ASF
7900 Harkins Road	Lanham, MD	60,000 SF	Another tenant who signed a lease prior to Children's took more space than originally leased, leaving insufficient space for Children's purposes

Expand Existing Locations in Prince George's County

Children's currently operates two outpatient centers in Prince George's County; one in Laurel and one in Upper Marlboro. The Laurel facility is 6,300 SF, and the Upper Marlboro facility is only 7,230 SF. Neither existing site afforded Children's the opportunity to expand due to lack of available space.

Summary and Ranking of Alternatives

Children's leadership evaluated the ability of each of the potential alternatives to meet the goals for the proposed project, on a numerical scale of one to five, in comparison to the proposed project. The results of this evaluation are summarized in the table below.

	Alternatives				
Goals	**Do Nothing**	**Build FS ASF**	**Build at Other Locations**	**Expand at Existing Locations**	**Proposed Project**
Create access to specialized surgical services for residents of Prince George's and surrounding Counties.	0	2	0	0	5
Provide state-of-the-art facilities to accommodate current patient need and plan for future demand.	0	3	0	0	5
Treat patients in the highest quality and most cost-effective setting.	2	4	0	0	5
Create additional capacity at Children's main campus to accommodate complex cases and anticipated growth.	0	4	0	0	5
Total Score	**2**	**13**	**0**	**0**	**20**

As evidenced in the score summarized above, the proposed project is the most reasonable and cost-effective method of addressing Children's goals and meeting the community's need.

10.24.01.08G(3)(d). Viability of the Proposal.

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.

INSTRUCTIONS: Please provide a complete description of the funding plan for the project, documenting the availability of equity, grant(s), or philanthropic sources of funds and demonstrating, to the extent possible, the ability of the applicant to obtain the debt financing proposed. Describe the alternative financing mechanisms considered in project planning and provide an explanation of why the proposed mix of funding sources was chosen.

- Complete Tables 3 and/or 4 below, as applicable. Attach additional pages as necessary detailing assumptions with respect to each revenue and expense line item.
- Complete Table L (Workforce) from the Hospital CON Application Table Package.
- Audited financial statements for the past two years should be provided by all applicant entities and parent companies to demonstrate the financial condition of the entities involved and the availability of the equity contribution. If audited financial statements are not available for the entity or individuals that will provide the equity contribution, submit documentation of the financial condition of the entities and/or individuals providing the funds and the availability of such funds. Acceptable documentation is a letter signed by an independent Certified Public Accountant. Such letter shall detail the financial information considered by the CPA in reaching the conclusion that adequate funds are available.
- If debt financing is required and/or grants or fund raising is proposed, detail the experience of the entities and/or individuals involved in obtaining such financing and grants and in raising funds for similar projects. If grant funding is proposed, identify the grant that has been or will be pursued and document the eligibility of the proposed project for the grant.
- Describe and document relevant community support for the proposed project.
- Identify the performance requirements applicable to the proposed project (see question 12, “Project Schedule”) and explain how the applicant will be able to implement the project in compliance with those performance requirements. Explain the process for completing the project design, obtaining State and local land use, environmental, and design approvals, contracting and obligating the funds within the prescribed time frame. Describe the construction process or refer to a description elsewhere in the application that demonstrates that the project can be completed within the applicable time frame(s).

Applicant Response

Children’s intends to finance the proposed project entirely through the use of current cash balances and liquid investments and does not anticipate the use of funds from grant programs or new or existing long-term debt. Although Children’s considered both of these sources (as opposed to utilizing existing funds held as cash or in liquid investments), the potential imposition of restrictive terms by the third-parties providing such funds could inhibit Children’s ability to develop a facility that delivers the services most critically needed in Prince George’s County and the surrounding communities.

Children's submits the information and documentation in the sections that follow regarding the financial and non-financial resources that will support the viability of the proposed project, for the consideration of the Commission.

Revenues and Expenses – Proposed Project (Table 4)
This table and all accompanying assumptions are included below.

Table 4				
	Projected (Ending with first full year at full utilization)[1]			
CY or FY (Circle)	CY 2020	CY 2021	CY 2022	CY 2023
1. Revenues				
a. Inpatient Services	$ -	$ -	$ -	$ -
b. Outpatient Services	12,142,499	13,856,411	25,316,997	26,141,125
c. Gross Patient Services Revenue	12,142,499	13,856,411	25,316,997	26,141,125
d. Allowance for Bad Debt	(202,032)	(230,549)	(421,188)	(434,850)
e. Contractual Allowance	(7,818,767)	(8,922,384)	(16,300,213)	(16,828,951)
f. Charity Care	(98,561)	(112,473)	(205,476)	(212,141)
g. Net Patient Care Service Revenues	4,023,139	4,591,005	8,390,120	8,665,183
h. Total Net Operating Revenue	$ 4,023,139	$ 4,591,005	$ 8,390,120	$ 8,665,183
2. Expenses				
a. Salaries, Wages, and Professional Fees, (including fringe benefits)	$ 2,908,647	$ 3,372,672	$ 5,153,512	$ 5,306,884
b. Contractual Services	20,249	20,755	21,274	21,806
c. Interest on Current Debt	-	-	-	-
d. Interest on Project Debt	-	-	-	-
e. Current Depreciation	-	-	-	-
f. Project Depreciation	1,169,321	1,169,321	1,169,321	1,169,321
g. Current Amortization	-	-	-	-
h. Project Amortization	-	-	-	-
i. Supplies	391,926	447,246	817,162	843,762
j. Other Expenses (Specify)	311,681	567,886	618,349	623,643
k. Total Operating Expenses	$ 4,801,823	$ 5,577,880	$ 7,779,617	$ 7,965,416
3. Income				
a. Income from Operation	(778,684)	(986,875)	610,503	699,767
b. Non-Operating Income	-	-	-	-
c. Subtotal	(778,684)	(986,875)	610,503	699,767
d. Income Taxes	-	-	-	-
e. Net Income (Loss)	$ (778,684)	$ (986,875)	$ 610,503	$ 699,767

Table 4 (Continued)				
CY or FY (Circle)	CY 2020	CY 2021	CY 2022	CY 2023
4. Patient Mix: A. Percent of Total Revenue				
1. Medicare	0.00%	0.00%	0.00%	0.00%
2. Medicaid	46.17%	46.17%	46.17%	46.17%
3. Blue Cross	27.48%	27.48%	27.48%	27.48%
4. Commercial Insurance	25.91%	25.91%	25.91%	25.91%
5. Self-Pay	0.17%	0.17%	0.17%	0.17%
6. Other (Specify)	0.27%	0.27%	0.27%	0.27%
7. TOTAL	100%	100%	100%	100%
B. Percent of Patient Days/Visits/Procedures (as applicable)				
1. Medicare	0.00%	0.00%	0.00%	0.00%
2. Medicaid	46.94%	46.94%	46.94%	46.94%
3. Blue Cross	26.69%	26.69%	26.69%	26.69%
4. Commercial Insurance	25.91%	25.91%	25.91%	25.91%
5. Self-Pay	0.23%	0.23%	0.23%	0.23%
6. Other (Specify)	0.23%	0.23%	0.23%	0.23%
7. TOTAL	100%	100%	100%	100%

[1]Children's will achieve full utilization of the proposed project in CY2022, the third year of operation.

The assumptions used to develop the projections in Table 4 are provided in the table below.

Assumptions	
1. Revenues	
a. Inpatient Services	
b. Outpatient Services	Volume has been discussed elsewhere in this application. Reimbursement for outpatient services is based upon Children's experience at the Montgomery County ASF.
c. Gross Patient Services Revenue	Based upon billing rates experienced at the Montgomery County ASF.
d. Allowance for Bad Debt	Based upon historical deductions experienced at the Montgomery County ASF.
e. Contractual Allowance	
f. Charity Care	
g. Net Patient Care Service Revenues	Calculated based upon 1(c) less the sum of 1(d), 1(e), and 1(f).
h. Total Net Operating Revenue	No additional operating revenue in excess of Net Patient Care Service Revenues is expected.
2. Expenses	
a. Salaries, Wages, and Professional Fees, (including fringe benefits)	Based on experience at the Montgomery County ASF as to the number of personnel needed for each staffing area. Rate of pay is based on market rates. Benefit expenses are calculated at 18% of salaries and wages, and are comparable to what is offered to similar staff at other Children's locations.
b. Contractual Services	Includes malpractice insurance expense, which is based upon experience at the Mongtomery County ASF.
c. Interest on Current Debt	N/A
d. Interest on Project Debt	N/A
e. Current Depreciation	N/A
f. Project Depreciation	Includes major movable equipment, which is depreciated over six years. New construction is depreciated over the twenty-year term of the lease.
g. Current Amortization	N/A
h. Project Amortization	N/A
i. Supplies	Includes medication and medical supplies expenses, based upon experience at the Montgomery County ASF.
j. Other Expenses (Specify)	Includes minor equipment, maintenance, lease and rental expenses, utilities, and other miscellaneous expenses. Lease expense is calculated based upon the terms of the lease; all other expenses are based upon experience at the Montgomery County ASF.
k. Total Operating Expenses	Calculated based upon sum of 2(a) through 2(j)

Workforce (Hospital CON Application Table L)
This table is included as Exhibit 19.

Audited Financial Statements
Audited financial statements for the past two (2) fiscal years, including reports of independent auditors, are included for Children's and its subsidiaries as Exhibit 20.

Debt Financing and Grant Funding
As Children's does not intend to finance the proposed project using funds provided through issuance of debt or solicitation of grand funds, this section is not applicable.

Community Support
Children's has an extensive history of, engagement with, and service to local communities as the premier provider of pediatric subspecialty care in the region. Close ties with local communities and leadership are critical to further Children's mission to "excel in Care, Advocacy, Research and Education." In planning and development of this project, a vast array of stakeholder groups has been engaged to provide guidance and feedback, as well as ensure the facility meets the needs of local patients and the medical community.

Stakeholders engaged include:

- Prince George's County Council, sitting as the Board of Health;
- Members of the Children's National at Prince George's County Advisory Board, including political, provider, and community representatives;
- Community based non-profit organizations;
- Physicians who will be practicing and providing services within the ASF and Regional Outpatient Center; and
- Other providers who serve patients in Prince George's County.

Community non-profit groups and local representatives share Children's vision and are supportive of the development of this ASF as a critical and needed service which is not currently offered in the community. They are confident that this proposed project will minimize the burden on members of the community's most vulnerable population, who are now required to travel significant distances through typically heavy traffic to receive similar services. Physicians and other providers are similarly excited about the potential to improve patient care, continuity, and satisfaction by offering high quality pediatric surgical services to their patients in Prince George's and the surrounding Counties.

Letters of Support
A wide range of stakeholders and community members have provided letters of support for the proposed project, including state delegates, health department officials, and leaders from local schools and health-related organizations, all of whom are excited about the increased access to care and economic impact to the local community. Physicians and other medical professionals also support the proposed project as a much-needed resource in the community for local patients:

> *"I routinely receive inquiries, from families, inquiring about available services in this area and have not been able to provide an adequate resource. This new facility will definitely fill a substantial medical void." – Dr. Michelle Jiggetts*

Perhaps the strongest voices of support for the new facility comes from local parents, who describe the significant and positive impact the project will have on local families:

> *"Having a Children's National Medical Outpatient Center close to our home would mean Dwight could get high quality medical care in our community and still attend school on appointment days, thus decreasing time out of school for him and his sister and time lost at work for us as parents."*

– Crystal Thomas

"Personally, as a full-time employee and a part-time student, I can meet her needs and continue pursuing my goals without having to choose one over the other, because I will be able to access everything in my neighborhood and eliminate the time consuming and costly commute." – Martha Herrera

"I am a parent of a wonderfully-made daughter with medical complexity… Quality service and care in a convenient location will help create a better quality of life." – Darcel T. Jackson

Further description of potential benefits to the community are detailed in the Letters of Support for the proposed project that are included as Exhibit 21.

Performance Requirements

The performance requirement that applies to the proposed project states that a new health care facility has up to 18 months from the date the CON is awarded to obligate 51% of the approved capital expenditure, and up to 18 months after the effective date of a binding construction contract to complete the project. A comprehensive project schedule has been developed that will allow the project to be implemented in compliance with these performance requirements.

- A submission to the Prince George's county towards site plan approval was made in November 2017. Following the anticipated planning board review in January 2018 and a District Council review, final approval is anticipated in April 2018.

- The building architectural and engineering design process commenced in October 2017. Base building construction drawings will be submitted for building permit approval in April 2018, with an anticipated base building permit to be issued in June 2018.

- The tenant improvement programming also commenced in October 2017 and tenant improvement/ interiors construction drawings will be submitted for building permit approval in May 2018, with anticipated tenant improvements building permit to be issued at the latest by August 2018.

- Site work and construction of the core and shell building is expected to begin in July 2018 and will take 10 months.

- Pending approval of the proposed project, a construction contract for the build-out of the ambulatory surgery center will be signed by August 30, 2018 and at least 51% of the approved capital expenditure will be obligated. Build-out will begin immediately after executing the contract, and is expected to be completed by October 2019, concurrent with the build-out of the rest of the services within the newly constructed building, with a total schedule of 11 months.

- A construction manager will be retained to manage the construction and complete the project within these performance requirements, as well as a tenant representative to ensure that the stakeholder decisions are made in a timely manner.

10.24.01.08G(3)(e). Compliance with Conditions of Previous Certificates of Need.

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.

INSTRUCTIONS: List all of the Maryland Certificates of Need that have been issued to the project applicant, its parent, or its affiliates or subsidiaries over the prior 15 years, including their terms and conditions, and any changes to approved Certificates that needed to be obtained. Document that these projects were or are being implemented in compliance with all of their terms and conditions or explain why this was not the case.

Applicant Response

One (1) Maryland Certificate of Need (CON) was issued to Children's during the time period requested (prior 15 years). This CON was issued in 2005 for the expansion of the existing ambulatory surgery services at the Children's Outpatient Center of Montgomery County by converting an existing procedure room to a sterile operating room, establishing a two-operating room facility.

This project was implemented and no changes to the approved CON were sought. The project was implemented in compliance with all terms and conditions applicable to the project.

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.

INSTRUCTIONS: Please provide an analysis of the impact of the proposed project. Please assure that all sources of information used in the impact analysis are identified and identify all the assumptions made in the impact analysis with respect to demand for services, payer mix, access to service and cost to the health care delivery system including relevant populations considered in the analysis, and changes in market share, with information that supports the validity of these assumptions. Provide an analysis of the following impacts:

a) On the volume of service provided by all other existing health care providers that are likely to experience some impact as a result of this project;

b) On the payer mix of all other existing health care providers that are likely to experience some impact on payer mix as a result of this project. If an applicant for a new nursing home claims no impact on payer mix, the applicant must identify the likely source of any expected increase in patients by payer.

c) On access to health care services for the service area population that will be served by the project. (State and support the assumptions used in this analysis of the impact on access);

d) On costs to the health care delivery system.

If the applicant is an existing facility or program, provide a summary description of the impact of the proposed project on the applicant's costs and charges, consistent with the information provided in the Project Budget, the projections of revenues and expenses, and the work force information.

Applicant Response

As noted throughout this Application, Children's believes that the subspecialized nature of the ambulatory pediatric care it provides is truly unique in the market. Children's care model includes attributes that are specifically geared toward providing high-quality care to the pediatric population, including (among others) the following:

- Pediatric physician subspecialists and surgeons
- Dedicated pediatric care teams, including nursing staff
- Provision of subspecialized physician support services (e.g., pediatric anesthesia)
- Facility layout, design, and aesthetics to address the needs of pediatric patients and families

As a result of these and other factors, including the fact that a substantial portion of the projected volume will result from the shift of cases within the system to address capacity constraints at the main campus, this proposed project will have minimal, if any, impact on other existing providers. The proposed project will, however, drastically improve access to quality pediatric surgical care for service area residents, particularly the Medicaid population.

Volume

Initial volume for the proposed project will be driven by a shift in cases from the main campus to the proposed facility. Additional volume will be driven by growth in market demand. Currently (as discussed in the Need Analysis discussed in Standard .05B(2)), a significant number of patients residing in the primary and secondary service area travel to Washington, DC for their outpatient surgical procedures due to a lack of services offered in the community today. By shifting outpatient surgical volume from the main hospital campus to the proposed facility closer to patients' homes, additional capacity will be created at the main campus to support more complex cases and the anticipated increase in demand from the rapidly growing population in the District and Northern Virginia. This shift in volume from one Children's outpatient facility to another will minimize any potential impact the new facility might have on existing providers.

Additional volume will be captured based on the anticipated growth in demand for pediatric ambulatory surgery services in the primary service area, overall, and particularly in Prince George's County. Sufficient growth in market demand is forecast to support volume projections at the proposed facility without adversely impacting existing providers. In general, the volume projected at the proposed facility assumes limited, if any shift in market share from other providers within the primary service area.

Furthermore, other ASF providers in the primary service area see a small proportion of pediatric patients. Based on the most recent data available[4], of the 95 ASF's in the primary service area, only 24 (25%) performed pediatric procedures (of any kind) in 2015. For those ASF providers who did perform pediatric procedures, pediatric patients accounted for less than 10% of total volume in 75% of facilities (and 94% of all ASFs). Therefore, any modest change in volume due to the availability of a specialized pediatric provider in the market would be negligible to any one provider.

The pediatric patient mix data for ASFs in the PSA, by county, between 2011 and 2015, are provided in the tables below.

Ambulatory Surgery Facility Pediatric Patient Mix: Prince George's County[1]

	Pediatric Patients (0-14 years old) as a % of Total						
Facility	CY 2009	CY 2010	CY 2011	CY 2012	CY 2013	CY 2014	CY 2015
Advantia Health Indian Creek Ambulatory Surgery Center	1%	1%	1%	0%	0%	0%	10%
Ambulatory Endoscopy Center of Maryland	0%	0%	0%	0%	0%	0%	0%
ASC Development Company, LLC - Bowie	0%	0%	0%	0%	0%	0%	0%
ASC Development Company, LLC - Greenbelt (Berwyn Heights)	0%	0%	0%	0%	0%	0%	0%
Belcrest Surgery Center, LLC	0%	0%	0%	1%	1%	0%	0%
Beltsville Ambulatory Surgery Center, Inc.	0%	0%	0%	0%	0%	0%	13%
Capital Endoscopy & Surgery Center	44%	33%	34%	29%	40%	37%	36%
College Park Surgery Center LLC	7%	5%	6%	5%	5%	5%	4%
Dimensions Surgery Center	0%	0%	0%	0%	0%	0%	0%
Forbes Ambulatory Surgery Center, LLC	0%	0%	0%	0%	0%	0%	3%
Greenbelt Endoscopy Center	0%	0%	0%	0%	0%	0%	0%
Greenbelt Urology Institute, LLC	1%	2%	3%	3%	2%	3%	4%
Hanover Parkway Surgery Center	6%	6%	6%	3%	6%	5%	5%
Harbor Surgery Center, LLC	0%	0%	0%	0%	0%	0%	0%
Harborside Surgery Center	0%	0%	0%	0%	0%	0%	0%
Hotchkiss and Katzen Ambulatory Surgical Center	2%	2%	5%	5%	4%	2%	4%
Kaiser Permanente Largo Medical Center ASC	0%	0%	0%	0%	0%	0%	1%
Laurel Foot and Ankle Surgery Center, Inc.	5%	5%	0%	2%	2%	3%	0%
Metropolitan Ambulatory Urologic Institute, LLC	0%	0%	3%	3%	3%	3%	2%
Mitchell A Barber, DPM, ASC, LLC	1%	2%	1%	2%	1%	1%	1%
Oxon Hill Endoscopy Center	0%	0%	0%	0%	0%	0%	0%
Oxon Hill Urology Surgery Center, PC	0%	3%	7%	5%	7%	9%	9%
Potomac View Surgery Center, LLC	1%	1%	25%	1%	1%	0%	0%
Prince George's Multispecialty Surgery Center	0%	0%	3%	2%	4%	3%	2%
Southern Maryland Endoscopy Center, LLC	0%	0%	0%	0%	0%	0%	0%
SurgCenter of Greenbelt, LLC	0%	0%	0%	0%	0%	0%	0%
SurgCenter of Southern Maryland, LLC	1%	0%	0%	0%	0%	0%	0%
Total Foot Care Surgery Center, Inc.	0%	0%	0%	0%	0%	0%	0%
University Center for Ambulatory Surgery	0%	0%	0%	0%	0%	0%	0%

[1]Source: State of Maryland, Health Care Comission Public Use Data (as of December 1, 2017).

[4] As reported by the Maryland Health Care Commission during the most recent data year, CY 2015.

Ambulatory Surgery Facility Pediatric Patient Mix: Anne Arundel County[1]							
	Pediatric Patients (0-14 years old) as a % of Total						
Facility	CY 2009	CY 2010	CY 2011	CY 2012	CY 2013	CY 2014	CY 2015
Annapolis Aesthetic Surgery	0%	0%	0%	0%	0%	0%	0%
Annapolis ENT Surgical Center, LLC	0%	0%	0%	0%	0%	0%	0%
Annapolis Surgery Center, L.L.C.	0%	0%	0%	0%	0%	0%	0%
Anne Arundel Digestive Center	0%	0%	0%	0%	0%	0%	0%
Anne Arundel Urological Surgery Center, LLC	63%	62%	62%	61%	62%	57%	56%
Arundel Ambulatory Surgery Center	0%	0%	3%	2%	2%	2%	2%
Arundel Mills Surgery Center, Inc.	0%	0%	0%	0%	0%	0%	0%
ASC at Waugh Chapel, Inc.	0%	0%	2%	5%	4%	5%	4%
ASC Development Company, LLC - Glen Burnie	10%	35%	19%	13%	7%	11%	10%
Baltimore Washington Eye Center	0%	0%	0%	0%	0%	0%	0%
Bay Surgery Center - Glen Burnie	0%	0%	0%	0%	0%	0%	0%
Bay Surgery Centers, LLC	0%	0%	0%	0%	0%	0%	0%
Center for Pain Medicine and Physiatric Rehabilitation	0%	0%	0%	0%	0%	0%	0%
Checkerspot Surgery Centers, LLC	0%	0%	0%	0%	0%	0%	0%
Chesapeake Ambulatory Surgery Center, LLC.	0%	0%	0%	0%	0%	0%	0%
Chesapeake Eye Surgery Center, LLC	0%	0%	0%	0%	0%	0%	0%
Dr. Samuel D. Beitler, Ambulatory Surgical Center	0%	0%	0%	0%	0%	0%	0%
EndoCentre at Quarterfield Station	0%	0%	0%	0%	0%	0%	0%
Jeffrey L. Bober, DPM, ASC	0%	0%	0%	0%	0%	0%	0%
Laser Surgery Center, Inc.	0%	0%	0%	1%	0%	0%	0%
Lisa Renfro Surgery Center, LLC	0%	0%	0%	0%	0%	0%	0%
Maryland Diagnostic & Therapeutic Endo Center	0%	0%	0%	0%	0%	0%	0%
Maryland Plastic Surgery, LLC	0%	0%	0%	0%	0%	0%	0%
Maryland Specialty Surgery Center, LLC	0%	0%	0%	0%	0%	0%	0%
MedSurg Foot Center	2%	2%	1%	1%	8%	0%	0%
Piney Orchard Surgery Center, LLC	0%	0%	0%	0%	0%	0%	0%
Plastic Surgery Specialists, PC	0%	0%	0%	0%	0%	0%	0%
Podiatry Group of Annapolis Ambulatory Surgical Center, LLC	3%	5%	4%	4%	3%	3%	3%
Riva Road Surgical Center, LLC	2%	2%	2%	1%	2%	1%	3%
River Reach Outpatient Surgery Center, LLC	0%	0%	0%	0%	0%	0%	0%
South River Ambulatory Surgery Center, LLC	0%	0%	0%	0%	0%	0%	0%
SurgCenter of Glen Burnie, LLC	0%	0%	0%	2%	0%	0%	0%
Surgery Center of Annapolis	0%	0%	15%	0%	0%	0%	0%
Surgical Center of Greater Annapolis, Inc.	0%	0%	0%	0%	0%	0%	0%
The Maryland Center for Digestive Health, LLC	0%	0%	1%	0%	0%	0%	0%
True Care ASC, LLC	0%	0%	0%	5%	6%	3%	2%

[1]Source: State of Maryland, Health Care Comission Public Use Data (as of December 1, 2017).

Ambulatory Surgery Facility Pediatric Patient Mix: Calvert County[1]							
	Pediatric Patients (0-14 years old) as a % of Total						
Facility	CY 2009	CY 2010	CY 2011	CY 2012	CY 2013	CY 2014	CY 2015
Calvert Ambulatory Foot Surgery Center	10%	10%	10%	5%	10%	15%	10%
Medstar Shah Medical Group-Prince Frederick	0%	0%	0%	0%	0%	0%	0%
Newbridge Surgery Center at Prince Frederick, LLC	0%	0%	0%	10%	0%	0%	0%
Plastic Surgery Center of Southern Maryland, LLC	0%	0%	0%	0%	0%	3%	2%
Prince Frederick Surgery Center, LLC	0%	0%	0%	0%	0%	0%	0%
The Surgery Center	0%	0%	0%	0%	0%	0%	0%
Advanced Pain Surgery Center, LLC	0%	0%	3%	4%	6%	8%	0%
ASC Development Company, LLC - Waldorf	0%	0%	0%	15%	7%	14%	8%
Bay Surgery Center - Waldorf, LLC	0%	0%	0%	0%	5%	1%	0%
Hotchkiss Surgical Center, LLC	0%	0%	0%	0%	0%	0%	0%
LaPlata Ambulatory Surgery Center	0%	0%	0%	0%	0%	0%	0%
Luxxery Corporation of Maryland	0%	0%	0%	0%	0%	0%	0%
Medstar Shah Medical Group-Waldorf	0%	0%	0%	0%	2%	0%	0%
Newbridge Surgery Center at Waldorf, LLC	5%	0%	0%	0%	0%	0%	0%
Summit Ambulatory Surgical Center, LLC	0%	0%	0%	0%	0%	0%	0%
Waldorf Endoscopy Center, ASC	0%	0%	0%	0%	0%	0%	0%

[1]Source: State of Maryland, Health Care Comission Public Use Data (as of December 1, 2017).

Ambulatory Surgery Facility Pediatric Patient Mix: Charles County[1]							
	Pediatric Patients (0-14 years old) as a % of Total						
Facility	CY 2009	CY 2010	CY 2011	CY 2012	CY 2013	CY 2014	CY 2015
Advanced Pain Surgery Center, LLC	0%	0%	0%	0%	0%	0%	0%
ASC Development Company, LLC - Waldorf	0%	0%	0%	0%	0%	0%	0%
Bay Surgery Center - Waldorf, LLC	0%	0%	0%	0%	0%	0%	0%
Hotchkiss Surgical Center, LLC	0%	0%	0%	0%	0%	0%	0%
LaPlata Ambulatory Surgery Center	0%	0%	0%	0%	0%	0%	0%
Luxxery Corporation of Maryland	0%	0%	0%	0%	0%	0%	0%
Medstar Shah Medical Group-Waldorf	0%	0%	0%	0%	0%	0%	0%
Newbridge Surgery Center at Waldorf, LLC	0%	0%	0%	0%	0%	0%	0%
Summit Ambulatory Surgical Center, LLC	0%	0%	0%	0%	0%	0%	1%
Waldorf Endoscopy Center, ASC	1%	0%	0%	0%	0%	0%	0%

[1]Source: State of Maryland, Health Care Comission Public Use Data (as of December 1, 2017).

Ambulatory Surgery Facility Pediatric Patient Mix: St. Mary's County[1]							
	Pediatric Patients (0-14 years old) as a % of Total						
Facility	CY 2009	CY 2010	CY 2011	CY 2012	CY 2013	CY 2014	CY 2015
Leonardtown Surgery Center, LLC	0%	0%	0%	0%	0%	0%	0%
Mechanicsville Ambulatory Surgery Center LLC	0%	0%	0%	0%	0%	0%	0%
Medstar Shah Medical Group-Hollywood	0%	0%	0%	1%	2%	1%	1%
St. Mary's MultiSpecialty Surgery Centre	0%	0%	0%	0%	0%	0%	0%

[1]Source: State of Maryland, Health Care Comission Public Use Data (as of December 1, 2017).

In Prince George's County, in only Advantia Health Indian Creek Ambulatory Surgery Center, Beltsville Ambulatory Surgery Center, Inc., and Capital Endoscopy and Surgery Center were 10% or more cases performed on pediatric patients in CY2015. Advantia Health Indian Creek Ambulatory Surgery Center (10% of cases), which opened in 2015, is currently a specialty obstetrics and gynecology surgery center and should not be materially impacted, if at all, by the proposed project. Beltsville Ambulatory Surgery Center, Inc. (13% of cases in 2015, the first year in which it reported cases on patients aged 0 - 14) is a physician-owned specialty foot and ankle surgery center staffed by podiatrists. Since Children's is not planning to have any podiatrists performing surgery in the proposed facility, Beltsville Ambulatory Surgery Center should not be materially impacted, if at all, by the proposed project. Capital Endoscopy and Surgery Center is a physician-owned specialty endoscopy surgery center. Although it reported that 36% of its cases in 2015 were performed on pediatric patients aged 0 – 14, it is not a specialty pediatric surgery center and is not staffed by specialized pediatric anesthesiologists, pediatric surgeons, or staff. In addition, Children's is only anticipating that one gastroenterologist will perform surgery at the proposed project, and volume for that physician is expected to represent only 6.5% of total cases in the first year of operation and 6.7% in the fourth year of operation. Accordingly, the proposed project should have minimal, if any impact on the Capital Endoscopy and Surgery Center.

In the rest of the primary service area, there are only three additional ASFs that reported 10% or more cases performed on pediatric patients in CY2015; Anne Arundel Urological Surgery Center, LLC, ASC Development Company, LLC – Glen Burnie, both in Anne Arundel County, and Calvert Ambulatory Foot Surgery Center in Calvert County. Anne Arundel Urological Surgery Center, LLC (56% in 2015) is a physician-owned, specialty urological surgery center located in Annapolis, MD, approximately 24 miles away from the proposed facility. It provides more routine urological surgery to pediatric patients and is not staffed by specialized pediatric anesthesiologists, pediatric surgeons, or staff. In addition, Children's is only anticipating that two urologists will perform surgery at the proposed project, and volume for those physicians is expected to represent only 14% of total cases in the first year of operation and 10% in the fourth year of operation. Accordingly, the proposed project should have minimal, if any impact on the Anne Arundel Urological Surgery Center. ASC Development Company, LLC – Glen Burnie (10% of cases in 2015) appears to be a physician-owned specialty spine and pain surgery center. It is not staffed by specialized pediatric anesthesiologists, pediatric surgeons, or staff. It is highly unlikely that the proposed project will have a material impact on this surgery center. Finally, Calvert Ambulatory Foot Surgery Center (10% of cases in 2015) is a physician-owned specialty podiatric surgery center. Since Children's is not planning to have any podiatrists performing surgery in the proposed facility, it should not have a material, if any impact on the Calvert Ambulatory Foot Surgery Center.

Based on this analysis of existing ambulatory surgery facilities in the primary service area, and on the fact that most of the volume projected for the proposed facility is expected to result from a shift in cases from Children's main campus to the new facility, the proposed project is expected to have limited, if any impact on other existing providers in the service area.

For a detailed analysis of proposed volume shifts within the Children's system and anticipated growth in market demand, see response to Standard .05B(2), above.

Payor Mix

Children's reiterates its longstanding organizational commitment to the region's most vulnerable population, as evidenced by its generous Financial Assistance Policy (discussed in response to Standard .05(A)(2) above and attached as Exhibit 9) and significant Medicaid payor mix of approximately 48%.

The proposed facility does not anticipate any changes in payer mix from Children's existing locations, as volume projections are driven by current patient mix and demographics. Further, since minimal, if any, volume impact is expected on area providers, minimal change is anticipated to the payer mix of those area providers. If anything, due to the high percentage of Medicaid patients to be served by the proposed facility, to the extent that some volume does shift from existing providers, payer mix at these providers may improve.

Access

The proposed project will have a dramatic impact on access to specialized pediatric subspecialty care in Prince George's and the surrounding Counties. Area residents that currently need to travel a significant distance for care through notoriously bad traffic will now have a convenient location in their community for ambulatory surgery. Geographically, there are no pediatric specialty ASFs in Prince George's County, and the closest locations for these residents are Children's other locations, the Montgomery County ASF (23 miles and 40 minutes' drive) and the main campus in Washington, D.C. (10 miles and 30 minutes' drive). Traveling this distance is particularly burdensome to pediatric patients and their families, many of whom are on Medicaid and may rely on public transportation. Having access to a high-quality local option will not only improve the satisfaction of this patient demographic, but also the likelihood they are able to receive ongoing and follow up care.

This project also enhances demographic access for those patients who are self-pay and in high deductible health plans, as having access to an ambulatory surgical option will result in less out-of-pocket costs than receiving inpatient care.

Delivery System

Reducing the overall cost of care for the healthcare delivery system, particularly to patients, is critical to Children's mission and is well-documented in the history of charity care provision of the institution. As previously noted, the projected volume for the proposed project is driven by volume shifts within the system, specifically from the ASF located at main hospital. Therefore, the proposed project is not anticipated to have significant impact on the direct cost of providing care.

However, one area of significant potential savings to the delivery system is the cost of care experienced by patients. In addition to the savings patients will experience if they are self-pay or in high deductible health plans discussed above, other out-of-pocket costs are also lowered for a community-based care option, as patients will have minimal or reduced costs in areas such as parking (which is free for the proposed project) and other costs related to travel/commuting a great distance, including the cost of accommodations, child care for other family members, etc.

Furthermore, while not specifically included in the analysis, some of the capacity created on the main campus could allow for additional future shifts in care from the inpatient to the outpatient setting, as technology and changes in care allow. This trend in shifting care generally to outpatient settings over time has the potential to significantly lower health system delivery costs.

As a result of these considerations, the proposed project is expected to have limited, if any, adverse impact on existing providers and a beneficial impact on the overall healthcare delivery system, particularly pediatric patients and their families.

Schedule of Exhibits

Exhibit	Description
1	Children's National Medical Center Organizational Chart
2	Children's National Medical Center: At a Glance (2017)
3	Lease Agreement
4	Project Drawings
5	Hospital CON Application, Table C
6	Hospital CON Application, Table E
7	List of Past Lease Activity
8	Authorization to Sign
9	Financial Assistance Policy
10	Charity Care Provided by Maryland ASFs
11	The Joint Commission Accreditation Certificate
12	Maryland Office of Health Care Quality License
13	Form of Transfer Agreement
14	Emergency Transfer Protocols
15	Service Area Definition
16	Service Area Demographic Summary
17	Certification of FGI Compliance
18	Marshall & Swift Valuation Service Benchmark Report
19	Hospital CON Application, Table L
20	Audited Financial Statements
21	Letters of Support