

VIRGINIA DEPARTMENT OF HEALTH
Office of Licensure and Certification
Division of Certificate of Public Need
Staff Analysis

November 21, 2022

COPN Request No. VA-8661

Virginia Commonwealth University Health System Authority
 Richmond, Virginia

Add One Cardiac Catheterization Lab in the Children's Tower at VCU Medical Center

Applicant

The Virginia Commonwealth University Health Systems Authority (VCUHS), doing business as VCU Medical Center, is a public body corporate and political subdivision of the Commonwealth of Virginia, governed by the Virginia Commonwealth University Health System Authority Act of 1996-Title 23, Chapter 6.2, 23-50.16:1 of the Code of Virginia. Subsidiaries of the applicant include MCV Associated Physicians, Community Memorial Hospital, University Health Services, Inc., Virginia Premier Health Plan, Inc., Rehab JV, LLC, and Virginia Children’s Care Network, LLC. VCUHS is located in Planning District (PD) 15, Health Planning Region (HPR) IV.

Background

VCUHS is, and has been for some time, in the process of constructing a purpose built “Children’s Tower” on the VCU Medical Center campus in downtown Richmond, Virginia. The Children’s Tower will be adjacent and connected to the new Children’s Hospital of Richmond (CHoR) Pavilion. Combined, the CHoR Pavilion and Children’s Tower will be the consolidated, on campus, home of all inpatient and outpatient pediatric care from within the campus (except neonatal general and special care and the psychiatric care currently at the Virginia Treatment Center for Children). The CHoR Pavilion and Children’s Tower complex will house pediatric outpatient clinics, computed tomography and magnetic resonance imaging, the pediatric emergency department, the Level 1 pediatric trauma center, and the Level 1 Children’s Surgery Center. VCUHS has an established pediatric cardiology program.

According to DCOPN records, there are 26 stationary cardiac catheterization laboratories in PD 15 (Table 1) at seven sites. VCU Medical Center is the only hospital in PD 15 performing pediatric cardiac catheterizations.

Table 1. PD 15 Cardiac Catheterization Laboratory Inventory: 2022

Facility	Cardiac Catheterization Labs
Bon Secours Memorial Regional Medical Center	4
Bon Secours St. Francis Medical Center	2
Bon Secours St. Mary's Hospital	4
Chippenham Hospital	6
Henrico Doctors' Hospital--Retreat	1
Henrico Doctors' Hospital--Forest	5
VCU Health System	4
Total	26

Source: DCOPN Records

Proposed Project

VCUHS proposes to expand its cardiac catheterization laboratory service with the addition of a fifth cardiac catheterization laboratory, devoted exclusively to pediatric patients and adult patients with congenital heart defects, in the new Children’s Tower on the hospital campus.

The total projected capital cost of the proposed project is \$6,205,961 (Table 2). The Children’s Hospital Foundation has committed to contributing at least \$5 million to fund the project, and the balance of the capital costs will be paid from the accumulated reserves of the applicant.

Accordingly, there are no financing costs associated with the proposed project. If approved, the applicant anticipates construction on the proposed project to begin January 1, 2023 and to be complete by May 31, 2023. The applicant anticipates an opening date by June 30, 2023.

Table 2. VCU Projected Capital Costs

Direct Construction Costs	\$2,539,491
Equipment Not Included in Construction Contract	\$3,283,721
Architectural and Engineering Fees	\$252,281
Other Consultant Fees	\$130,469
Total	\$6,205,961

Source: COPN Request No. VA-8661

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as “The addition by an existing medical care facility described in subsection A of any new medical equipment for the provision of cardiac catheterization...” A medical care facility includes “any facility licensed as a hospital, as defined in § 32.1-123.”

Required Considerations -- § 32.1-102.3, of the Code of Virginia

In determining whether a public need exists for a proposed project, the following factors shall be taken into account when applicable.

- 1. The extent to which the proposed project will provide or increase access to health care services for people in the area to be served and the effects that the proposed project will have on access to health care services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to health care;**

Geographically, VCU Medical Center is located at 1000 East Broad Street, Richmond, Virginia, in proximal to Interstates 95 and 64. Additionally, the VCU Medical Center campus is served by public transportation, including the GRTC Pulse system – a modern high quality, high-capacity rapid transit system that serves a 7.6-mile route along Broad Street and Main Street, two major thoroughfares in the city of Richmond. There is a Pulse station on the same block as the Children’s Tower, at its Broad Street entrance.

Regarding socioeconomic barriers to access to the applicant’s services, according to regional and statewide data regularly collected by Virginia Health Information (VHI), for 2020, the most recent year for which such data is available, the average amount of charity care provided by HPR

IV facilities was 1.3% of all reported total gross patient revenues (Table 3). DCOPN notes that recent changes to §32.1-102.4B of the Code of Virginia now require DCOPN to place a charity care condition on all applicants seeking a COPN. For this reason, DCOPN recommends that the proposed project, if approved, be subject to the applicant’s agreement to a 1.3% charity care condition to be derived from total cardiac catheterization gross patient services revenue as well as well as agreement to provide care to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et seq; and to facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area,.

Table 3. HPR IV Charity Care Contributions: 2020

2020 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue
Bon Secours St. Francis Medical Center	\$909,600,664	\$28,930,399	3.18%
Bon Secours Richmond Community Hospital	\$916,350,189	\$28,612,659	3.12%
Bon Secours St. Mary's Hospital	\$2,028,786,995	\$51,459,409	2.54%
Bon Secours Memorial Regional Medical Center	\$1,425,167,696	\$28,386,279	1.99%
Centra Southside Community Hospital	\$324,125,273	\$5,447,210	1.68%
Sentara Halifax Regional Hospital	\$279,469,170	\$3,668,115	1.31%
CJW Medical Center	\$7,560,037,769	\$86,592,596	1.15%
VCU Health System	\$6,172,966,084	\$69,698,687	1.13%
John Randolph Medical Center	\$1,032,491,952	\$10,903,791	1.06%
Henrico Doctors' Hospital	\$4,859,466,138	\$51,444,601	1.06%
VCU Community Memorial Hospital	\$317,168,977	\$1,932,837	0.61%
Bon Secours Southern Virginia Regional Medical Center	\$183,898,466	\$1,059,319	0.58%
Bon Secours Southside Regional Medical Center	\$1,875,804,250	\$5,837,542	0.31%
Vibra Hospital of Richmond LLC	\$145,408,947	\$0	0.00%
Cumberland Hospital for Children and Adolescents	\$54,279,874	\$0	0.00%
Total Facilities			15
Median			1.1%
Total \$ & Mean %	\$28,085,022,444	\$373,973,444	1.3%

Source: VHI (2020)

Table 4 shows projected population growth in PD 15 through 2030. As depicted in Table 4, at an average annual growth rate of 1.01%, PD 15’s population growth rate from 2010-2020 was well above the state’s average annual growth rate of 0.77%. Overall, the planning district was projected to add an estimated 108,937 people in the 10-year period ending in 2020—an approximate 11% increase with an average increase of 10,893 people annually. In the 10-year period ending in 2030, the planning district is projected to add an estimated 108,303 people – an approximate 10% increase with an average increase of 10,830 people annually.

Table 4. Statewide and PD 15 Population Projections: 2010-2030

Locality			2010 - 2020		2030	2020 - 2030	
	2010	2020	% Change	Avg Ann % Change		% Change	Avg Ann % Change
Charles City	7,256	6,982	-3.78%	-1.51%	6,941	-0.59%	0.06%
Chesterfield	316,236	353,841	11.89%	1.10%	396,647	12.10%	1.15%
Goochland	21,717	23,547	8.43%	0.79%	26,702	13.40%	1.27%
Hanover	99,863	109,244	9.39%	0.88%	119,360	9.26%	0.89%
Henrico	306,935	332,103	8.20%	0.77%	363,259	9.38%	0.90%
New Kent	18,429	23,474	27.38%	2.39%	28,104	19.72%	1.82%
Powhatan	28,046	29,909	6.64%	0.63%	33,440	11.81%	1.12%
Richmond City	204,214	232,533	13.87%	1.28%	245,483	5.57%	0.54%
Total PD 15	1,002,696	1,111,633	10.86%	1.01%	1,219,936	9.74%	0.93%
PD 15 65+	116,609	172,249	47.72%	3.88%	224,417	30.29%	2.68%
Virginia	8,001,024	8,655,021	8.17%	0.77%	9,331,666	7.82%	0.76%
Virginia 65+	976,937	1,352,448	38.44%	3.22%	1,723,382	27.43%	2.45%

Source: U.S. Census, Weldon Cooper Center Projections (June 2019) and DCOPN (interpolations)

DCOPN did not identify any other unique geographic, socioeconomic, cultural, transportation, or other barriers to care in the planning district.

2. The extent to which the proposed project will meet the needs of the people in the area to be served, as demonstrated by each of the following:

- (i) The level of community support for the proposed project demonstrated by people, businesses, and governmental leaders representing the area to be served;**

The applicant provided a letter of support for the requested project from Dr. Marlon Levy, (VCU Medical Center’s Chief Medical Officer and from Ms. Lauren Zaller Moore, (President and CEO of Children’s Hospital Foundation).

DCOPN is unaware of any opposition to the proposed project.

Public Hearing

Section 32.1-102.6 B of the Code of Virginia directs DCOPN to hold one public hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city in the case of competing applications; or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. COPN Request No. VA-8661 is not competing with another project in this batch cycle and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing was held.

- (ii) The availability of reasonable alternatives to the proposed project that would meet the needs of the people in the area to be served in a less costly, more efficient, or more effective manner;**

The applicant is the sole provider of pediatric cardiac catheterization services in PD 15. As such, there is no alternative location in PD 15 to direct pediatric patients for care. The closest

alternative sites are in Norfolk and Charlottesville. Maintaining the status quo is always an alternative, but in the case, not a reasonable one. The applicant's cardiac catheterization volume has exceeded the volume threshold needed to demonstrate a need for additional capacity. There is no alternative to the project.

(iii) Any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6;

Currently, there is no organization in HPR IV designated by the Virginia Department of Health to serve as Health Planning Agency for PD 15. Therefore, this consideration is not applicable to the review of either proposed project.

(iv) Any costs and benefits of the proposed project;

As illustrated in Table 2, the total projected capital cost of the proposed project is \$6,205,961. At least \$5,000,000 will be funded from a gift from the Children's Hospital Foundation, with the balance funded using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with this project.

DCOPN concludes that the costs for the proposed project are reasonable and consistent with previously approved projects similar in clinical scope. COPN No. VA-4768 authorized the addition of one cardiac catheterization laboratory, at Mary Washington Hospital at a cost of \$3,521,088. The Mary Washington Hospital project was to retrofit an existing 1,000 square foot electrophysiology laboratory for cardiac catheterization services and cost \$1,049,400 (\$1,049 per square foot). The VCUHS budgeted direct construction cost for the new build out of approximately 1,046 square feet of new construction is \$2,539,491 (\$2,038 per square foot). Equipment cost for the Mary Washington Hospital project was \$2,328,700, 71% of the VCUHS equipment cost of \$3,283,721.

With regard to benefits of the proposed project, the applicant reiterates that there is a unique institutional need for the addition of a cardiac catheterization laboratory as the existing laboratories have operated above 100% of the SMFP threshold for expansion. VCUHS is building the Children's Tower, which in concert with the CHoR Pavilion will result in a purpose built pediatric health care facility. The proposed cardiac catheterization laboratory will be located in this pediatric specific facility. To continue to transport children out of the pediatric facility across campus to intermingle with the adult cases in the existing laboratories is at cross purposes with the goals of establishing the pediatric facility. Within the Children's Tower the architecture, equipment, supplies and staff will be specifically oriented to the care of children.

(v) The financial accessibility of the proposed project to the people in the area to be served, including indigent people; and

The applicant has provided assurances that cardiac catheterization services will be accessible to all patients, regardless of financial considerations. Furthermore, the Pro Forma Income Statement provided by the applicant anticipates a charity care contribution equal to 1.04% of gross revenues derived from cardiac catheterization services at VCU Medical Center, an amount less than the

average HPR IV contribution of 1.3% and less than VCUHS's 2020 contribution of 1.13% reported to VHI for 2020. Recent changes to §32.1-102.4B of the Code of Virginia now require the State Health Commissioner to place a charity care condition on all applicants seeking a COPN. For this reason, DCOPN recommends that the proposed project, if approved, be subject to a charity care condition at the regional average of 1.3%, to be derived from total cardiac catheterization gross patient services revenue. DCOPN again notes that its recommendation includes a provision allowing for the reassessment of the charity care rate at such time as more reliable data becomes available regarding the full impact of Medicaid expansion in the Commonwealth.

- (vi) **At the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a proposed project;**

Section 32.1-102.2:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop, by November 1, 2022, recommendations for a comprehensive State Health Services Plan (SHSP). In the interim, DCOPN will consider the consistency of the proposed projects with the predecessor of the SHSP, the State Medical Facilities Plan (SMFP).

3. The extent to which the proposed project is consistent with the State Health Services Plan;

The State Medical Facilities Plan (SMFP) contains the standards and criteria for the addition of cardiac catheterization services. They are as follows:

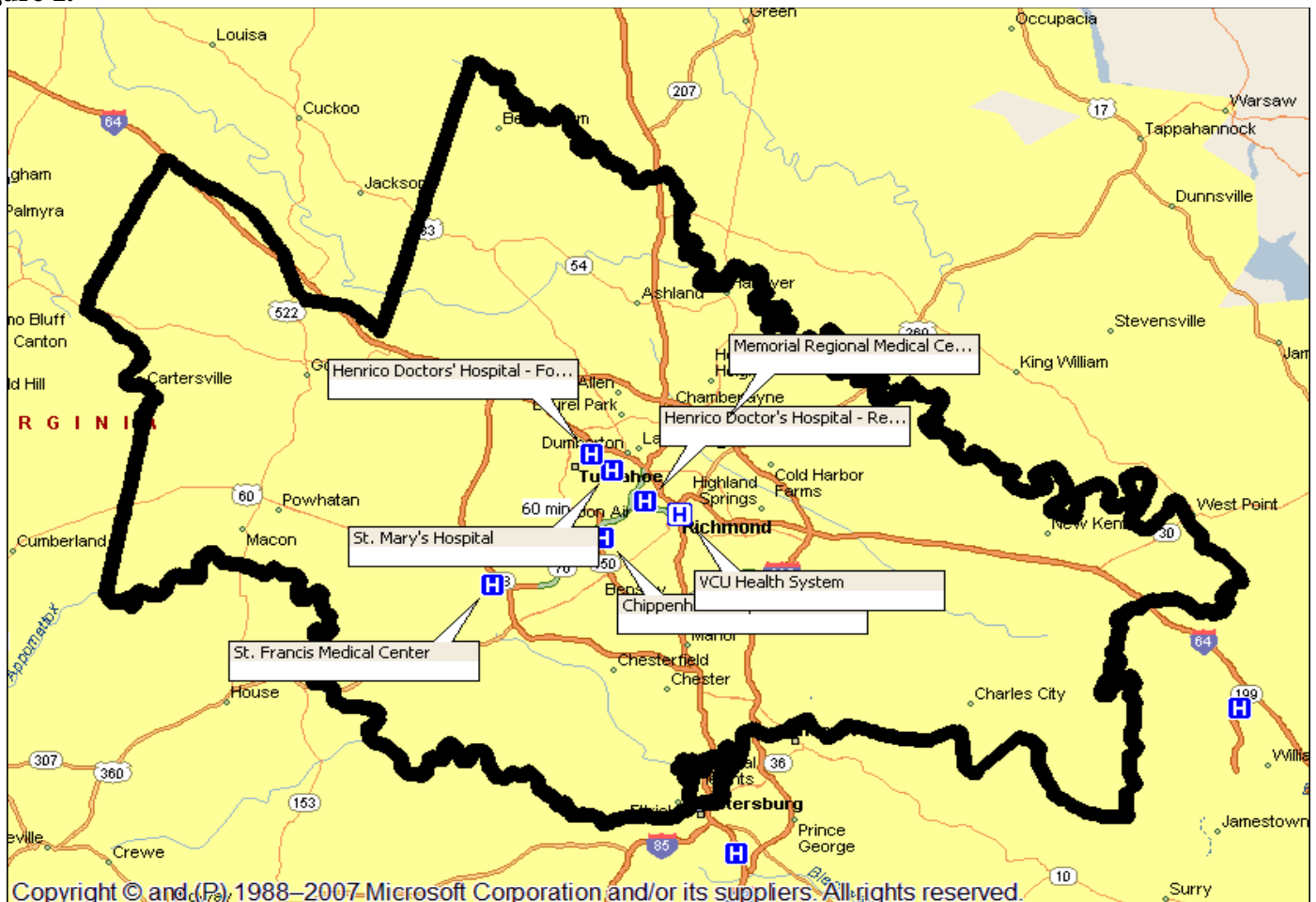
Part IV. Cardiac Services
Article 1. Criteria and Standards for Cardiac Catheterization Services

12VAC5-230-380. Travel time.

Cardiac catheterization services should be within 60 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the commissioner.

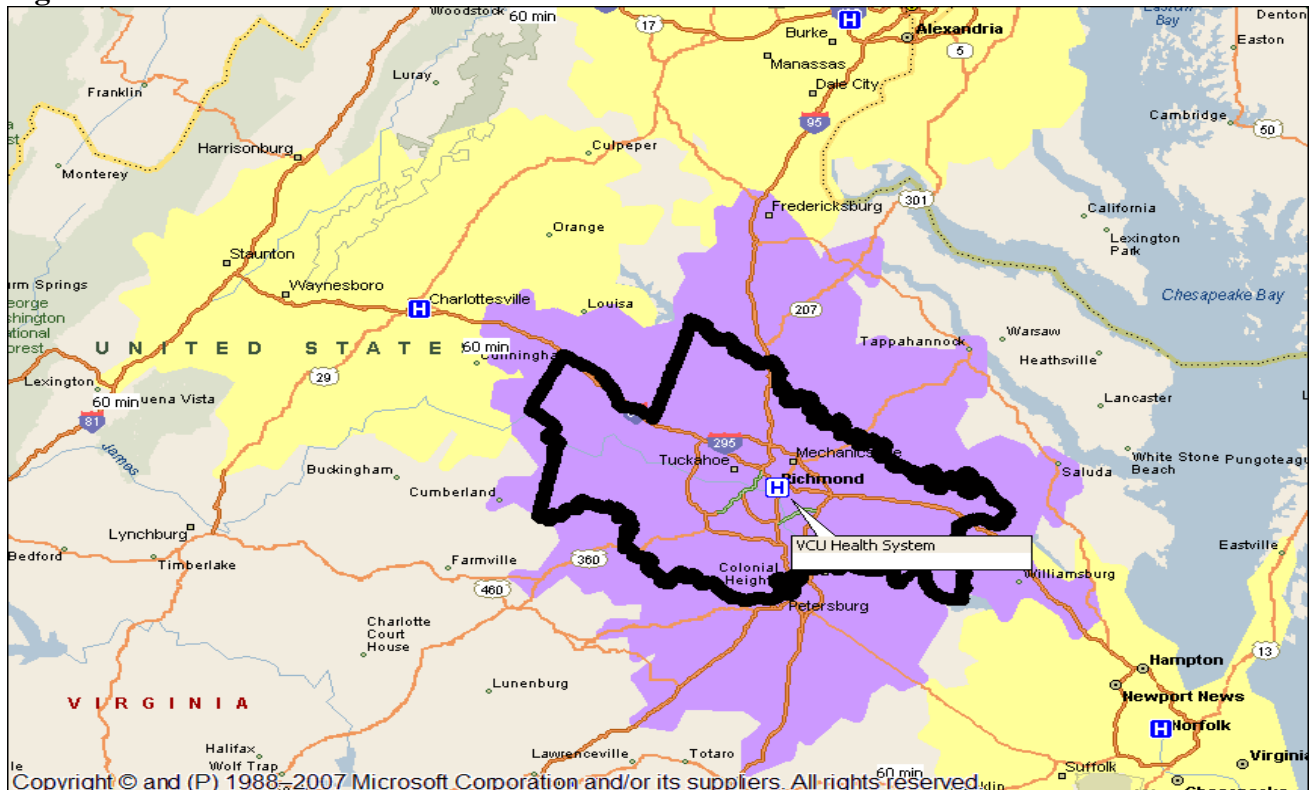
The heavy black line in Figure 1 identifies the boundaries of PD 15. The white "H" sign marks the location of the proposed project, while the blue "H" signs mark the locations of all other existing PD 15 providers of cardiac catheterization services. The yellow shading illustrates the area that is within a 60-minute drive under normal driving conditions of cardiac catheterization services. Based on the amount and location of this shading, it is evident that cardiac catheterization services are already well within a 60 minute drive under normal condition for all residents of PD 15. Furthermore, DCOPN again notes that the applicant is a current provider of cardiac catheterization services, and accordingly, approval of the proposed project would not improve geographic access to this service for the residents of PD 15 in any meaningful way. However, as the applicant cites an institutional need for the proposed additional lab, DCOPN contends that geographic access is not the factor that prevents the VCUMC patient population from receiving timely access to care.

Figure 1.



The heavy black line in Figure 2 identifies the boundaries of PD 15. The white “H” sign marks the location of the proposed project, while the blue “H” signs mark the locations of all other existing providers of pediatric cardiac catheterization services in the area. The lavender shading illustrates the area that is within a 60-minute drive under normal driving conditions of pediatric cardiac catheterization services provided by the applicant. The yellow shading represents the area that is within a 60-minute drive under normal driving conditions of pediatric cardiac catheterization services provided by other area hospitals. Based on the amount and location of this shading, it is evident that pediatric cardiac catheterization services are already well within a 60 minute drive under normal condition for all residents of PD 15. Furthermore, DCOPN notes that the applicant is the current provider of pediatric cardiac catheterization services in PD 15, and accordingly, approval of the proposed project would not improve geographic access to this service for the residents of PD 15.

Figure 2



12VAC5-230-390. Need for new service.

- A. No new fixed site cardiac catheterization service should be approved for a health planning district unless:**
- 1. Existing fixed site cardiac catheterization services located in the health planning district performed an average of 1,200 cardiac catheterization DEPs per existing and approved laboratory for the relevant reporting period;**
 - 2. The proposed new service will perform an average of 200 DEPs in the first year of operation and 500 DEPs in the second year of operation; and**
 - 3. The utilization of existing services in the health planning district will not be significantly reduced.**
- B. Proposals for mobile cardiac catheterization laboratories should be approved only if such laboratories will be provided at a site located on the campus of an inpatient hospital. Additionally, applicants for proposed mobile cardiac catheterization laboratories shall be able to project that they will perform an average of 200 DEPs in the first year of operation and 350 DEPs in the second year of operation without significantly reducing the utilization of existing laboratories in the health planning district below 1,200 procedures.**
- C. Preference may be given to a project that locates new cardiac catheterization services at an inpatient hospital that is 60 minutes or more driving time one way under normal conditions of existing services if the applicant can demonstrate that the proposed new laboratory will perform an average of 200 DEPs in the first year of operation and 400**

DEPs in the second year of operation without significantly reducing the utilization of existing laboratories in the health planning district.

Not applicable. The applicant is not proposing to establish a new cardiac catheterization service, but rather are proposing to expand existing services, citing an institutional need.

12VAC5-230-400. Expansion of services.

Proposals to increase cardiac catheterization services should be approved only when:

- 1. All existing cardiac catheterization laboratories operated by the applicant’s facilities where the proposed expansion is to occur have performed an average of 1,200 DEPs per existing and approved laboratory for the relevant reporting period; and**
- 2. The applicant can demonstrate that the expanded service will achieve an average of 200 DEPs per laboratory in the first 12 months of operation and 400 DEPs in the second 12 months of operation without significantly reducing the utilization of existing cardiac catheterization laboratories in the health planning district.**

Table 5 illustrates the utilization of PD 15 cardiac catheterization laboratories in 2020. Reporting to VHI, for 2020, does not reflect the revised DEP calculations that distinguish simple from complex therapeutic (Rx) procedures. The difference is that a complex therapeutic catheterization is valued at 2 DEPs more than a simple therapeutic catheterization, which compounds to a 6 DEP difference per catheterization for pediatric cases.

Table 5. 2020 PD 15 Diagnostic Equivalent Procedures¹

Facility Name	Cardiac Catheterization Laboratories	Diagnostic Equivalent Procedures (DEP)					Total	Utilization
		Adult Dx	Adult Rx	Adult Same Visit	Ped Dx	Ped Rx		
Bon Secours Memorial Regional Medical Center ²	3	998	148	2,424	-	-	3,570	99.17%
Bon Secours St. Francis Medical Center	2	660	70	708	-	-	1,438	59.92%
Bon Secours St. Mary's Hospital	4	1,154	108	1,755	-	-	3,017	62.85%
Chippenham Hospital	6	2,119	1,670	2,418	-	-	6,207	86.21%
Henrico Doctor's Hospital - Retreat	1	-	-	-	-	-	-	0.00%
Henrico Doctors' Hospital - Forest	5	1,555	1,014	1,548	-	-	4,117	68.62%
VCU Medical Center	4	2,893	1,546	-	20	104	4,563	95.06%
Total	25	9,379	4,556	8,853	20	104	22,912	76.37%

1 Reporting to Virginia Health Information, for 2020, does not reflect the revised DEP calculations that distinguish simple from complex therapeutic (Rx) procedures. The difference is that a complex therapeutic catheterization is valued at 2 DEPs more than a simple therapeutic catheterization, which compounds to a 6 DEP difference per catheterization for pediatric cases.

2 Bon Secours Memorial Regional Medical Center received COPN authorization (COPN No. VA-04709) to add a 4th cardiac catheterization laboratory, as an OR/lab hybrid. The 4th lab did not become operational until July 2021, therefore there is no utilization reported for 2020.

Source: Virginia Health Information 2020 Data

Without providing detailed numbers behind their calculation, VCUHS provided a chart showing that in 2020, using the current values for DEPs, VCU Medical Center performed 4,833 cardiac catheterization DEPs, for a 100.7% utilization of the SMFP’s 1,200 DEPs per laboratory expansion standard, and 108.1% in 2021 (unreported by VHI). No specific breakdown between pediatric and

adult cases was provided. Given the magnitude of the difference in DEP value between simple and complex therapeutic cardiac catheterizations it is reasonable to accept the higher values independently reported by VCUHS.

Using the VCUHS reported total DEPs and the VHI reported volume, (which does distinguish between adult and pediatric cardiac catheterizations), a proxy was developed to estimate the DEPs provided by the applicant and within PD 15. To achieve close to the 100.7% VHI the proportion of adult to pediatric simple to complex cardiac catheterizations would need to be approximately 85% to 15%. For the estimate it was assumed that all PD 15 providers of therapeutic (interventional) cardiac catheterizations performed complex as well as simple procedures at the same proportion of 85% simple. It was also assumed that all complex cardiac catheterizations were performed on inpatients. The result, (Table 6), shows a small increase in overall utilization PD wide

Table 6. PD 15 Diagnostic Equivalent Procedures ¹

Facility Name	Cardiac Cath Labs	Diagnostic Equivalent Procedures (DEPs)							Utilization
		Adult Dx	Adult Rx	Adult Same Visit	Adult Total	Ped Dx	Ped Rx	Total	
Bon Secours Memorial Regional Medical Center ²	3	998	181	2,424	3,603	-	-	3,603	100.1%
Bon Secours St. Francis Medical Center	2	660	79	708	1,447	-	-	1,447	60.3%
Bon Secours St. Mary's Hospital	4	1,154	118	1,755	3,027	-	-	3,027	63.1%
Chippenham Hospital	6	2,119	1,877	2,418	6,414	-	-	6,414	89.1%
Henrico Doctor's Hospital - Retreat	1	-	-	-	-	-	-	-	0.0%
Henrico Doctors' Hospital - Forest	5	1,555	1,128	1,548	4,231	-	-	4,231	70.5%
VCU Medical Center	4	2,893	1,863	-	4,756	20	106	4,882	101.7%
Total	25	9,379	5,246	8,853	23,478	20	106	23,604	78.7%

¹ VHI 2020 data recalculated assuming 85% of adult and pediatric therapeutic cardiac catheterization procedures were simple and 15% were complex for the purposes of calculating DEPs.

² Bon Secours Memorial Regional Medical Center received COPN authorization (COPN No. VA-04709) to add a 4th cardiac catheterization laboratory, as an OR/lab hybrid. The 4th lab did not become operational until July 2021, therefore there is no utilization reported for 2020.

Source: VHI 2020 Data and DCOPN Calculations

Using the calculations to achieve the estimates in Table 6 the total DEPS at VCUHS's cardiac catheterization program was 1,220 DEPs, or 101.7% of the standard required for expansion (1,200 DEPs). That element of this SMFP criteria is met.

Using the calculations to achieve the estimates in Table 6 the total pediatric DEPS at VCUHS was 120 DEPs. This is 60% of the 200 DEP threshold for the first year of operation. The DEPs attributed to the proposed cardiac catheterization laboratory include only pediatric cases, but not adults with congenital heart defects. VCUHS did not provide any indication of how many adult congenital heart defect cases are expected. It is unlikely the adult congenital heart defect case load would be two thirds of the pediatric case load, providing the additional 80 DEPs needed to reach the 120 DEPs in the first year. Without explanation the applicant projects that the pediatric cardiac catheterization laboratory will perform 537 DEPs in the first year of operation and 860 DEPs in the second year of operation. Without further context it would seem unlikely the pediatric (and adult congenital heart defect) caseload would increase by 448% over the 2020 reported level. Over all,

the combined existing “adult” labs and the new “pediatric” lab are expected to continue to average over 1,200 DEPs per year.

12VAC5-230-410. Pediatric cardiac catheterization.

No new or expanded pediatric cardiac catheterization services should be approved unless:

- 1. The proposed service will be provided at an inpatient hospital with open heart surgery services, pediatric tertiary care services or specialty or subspecialty level neonatal special care;**
- 2. The applicant can demonstrate that the proposed laboratory will perform at least 100 pediatric cardiac catheterization procedures in the first year of operation and 200 pediatric cardiac catheterization procedures in the second year of operation; and**
- 3. The utilization of existing pediatric cardiac catheterization laboratories in the health planning district will not be reduced below 100 procedures per year.**

VCUHS is a tertiary level academic inpatient hospital with a robust cardiac surgery program, with three dedicated cardiac surgery ORs. In 2020 VHI reported VCUHS performed 814 cardiac surgery cases, 28 of which were pediatric.

As reported to VHI, VCUHS had 36 pediatric cardiac catheterization visits in 2020. Again, without explanation VCUHS projects 123 pediatric cardiac catheterization procedures in the first year of operation of the new laboratory, 3.4 times the number of visits reported to VHI for 2020, and 200 in the second year, 5.5 times the 2020 reported volume.

As VCUHS is the sole provider of pediatric cardiac catheterization services in PD 15, the expansion to a fifth cardiac catheterization laboratory at VCUHS, enabling to devotion on one laboratory to pediatric cardiac catheterizations, will not adversely impact other providers.

12VAC5-230-420. Nonemergent cardiac catheterization.

A. Simple therapeutic cardiac catheterization. Proposals to provide simple therapeutic cardiac catheterization are not required to offer open heart surgery service available on-site in the same hospital in which the proposed simple therapeutic service will be located. However, these programs shall adhere to the requirements described in subdivisions 1 through 9 of this subsection.

The programs shall:

- 1. Participate in the Virginia Heart Attack Coalition, the Virginia Cardiac Services Quality Initiative, and the Action Registry-Get with the Guidelines or National Cardiovascular Data Registry to monitor quality and outcomes;**
- 2. Adhere to strict patient-selection criteria;**
- 3. Perform annual institutional volumes of 300 cardiac catheterization procedures, of which at least 75 should be percutaneous coronary intervention (PCI) or as dictated by American College of Cardiology (ACC)/American Heart Association (AHA) Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories effective 1991;**

4. Use only AHA/ACC-qualified operators who meet the standards for training and competency;
 5. Demonstrate appropriate planning for program development and complete both a primary PCI development program and an elective PCI development program that includes routine care process and case selection review;
 6. Develop and maintain a quality and error management program;
 7. Provide PCI 24 hours a day, seven days a week;
 8. Develop and maintain necessary agreements with a tertiary facility that must agree to accept emergent and nonemergent transfers for additional medical care, cardiac surgery, or intervention; and
 9. Develop and maintain agreements with an ambulance service capable of advanced life support and intra-aortic balloon pump transfer that guarantees a 30-minute or less response time.
- B. Complex therapeutic cardiac catheterization. Proposals to provide complex therapeutic cardiac catheterization should be approved only when open heart surgery services are available on-site in the same hospital in which the proposed complex therapeutic cardiac catheterization programs will be required to participate in the Virginia Cardiac Services Quality Initiative and the Virginia Heart Attack Coalition.**

As the applicant is not proposing to provide only simple therapeutic cardiac catheterization, this provision is not applicable.

12VAC5-230-430. Staffing.

- A. Cardiac catheterization services should have a medical director who is board certified in cardiology and has clinical experience in performing physiologic and angiographic procedures.**

In the case of pediatric cardiac catheterization services, the medical director should be board-certified in pediatric cardiology and have clinical experience in performing physiologic and angiographic procedures.

- B. Cardiac catheterization services should be under the direct supervision of one or more qualified physicians. Such physicians should have clinical experience in performing physiologic and angiographic procedures.**

Pediatric catheterization services should be under the direct supervision of one or more qualified physicians. Such physicians should have clinical experience in performing pediatric physiologic and angiographic procedures.

The applicant did not address the staffing standard, however, as an academic medical center with a long history of providing cardiac care to adults, children and neonates, VCUHS has the appropriate staff.

The SMFP also contains criteria/standards for when institutional expansion is needed. They are as follows:

12VAC5-230-80. When institutional expansion needed.

- A. Notwithstanding any other provisions of this chapter, the commissioner may grant approval for the expansion of services at an existing medical care facility in a health planning district with an excess supply of services when the proposed expansion can be justified on the basis of a facility's need having exceeded its current service capacity to provide such service or on the geographic remoteness of the facility.**
- B. If a facility with an institutional need to expand is part of a health system, the underutilized services at other facilities within the health system should be reallocated, when appropriate, to the facility with the institutional need to expand before additional services are approved for the applicant. However, underutilized services located at a health system's geographically remote facility may be disregarded when determining the institutional need for the proposed project.**
- C. This section is not applicable to nursing facilities pursuant to § 32.1-102.3:2 of the Code of Virginia.**
- D. Applicants shall not use this section to justify a need to establish new services.**

The SMFP standards for expansion of an existing cardiac catheterization service are based on the applicant performing 1,200 DEPs per laboratory annually. In 2020, VCUMC's cardiac catheterization service performed 1,220 DEPs, (using the proxy estimate in Table 6) and as such, operated at 101.7% of the 1,200 DEPs advocated by the SMFP as the minimum utilization level required for justifying an institution specific need to expand a cardiac catheterization services. No other hospital affiliated with VCUMC provides cardiac catheterization, so there is no underutilized capacity available for transfer. The applicant is not a nursing home nor does this request represent an attempt to establish a new cardiac catheterization service. Accordingly, DCOPN concludes that no reasonable alternative to the proposed project exists and that the applicant has adequately demonstrated a unique institutional need for the proposed expansion.

Eight Required Considerations Continued

- 4. The extent to which the proposed project fosters institutional competition that benefits the area to be served while improving access to essential health care services for all people in the area to be served;**

The applicant is an established provider of cardiac catheterization services in PD 15 and is the sole provider of pediatric cardiac catheterization services in PD 15, and in HPR IV. Furthermore, the applicant cites a unique institutional need for the proposed expansion. DCOPN notes that the proposed project would not introduce a new service provider or a new service delivery site to PD 15. Accordingly, DCOPN concludes that the project is not intended to, nor likely to, foster institutional competition that benefits the area to be served.

- 5. The relationship of the proposed project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities;**

The applicant is the sole provider of pediatric cardiac catheterization in not only PD 15 but in HPR IV. The applicant is also the area's sole tertiary academic medical center and the area's

comprehensive pediatric center. With one other exception all the cardiac catheterization laboratories in PD 15 are operating at below 90% of the SMFP's threshold of 1,200 DEPs (Table 6).

6. The feasibility of the proposed project, including the financial benefits of the proposed project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital;

The capital costs and the expected revenue to be derived from the applicant's cardiac catheterization service are reasonable and will support the financial viability of the program and the proposed project.

With regard to staffing, the applicant will continue to use the existing pediatric specific cardiac catheterization staff from the existing laboratories in the new laboratory to be located in the Children's Tower. The applicant only a minor, non-specified need to hire additional staff for the proposed project. The applicant is an established provider of cardiac catheterization services with an existing employee recruitment and retention program. Recruitment of additional health care staff is posing a challenge not only locally but nationwide giving concern as to the applicant's ability to recruit and retain the needed staff.

7. The extent to which the proposed project provides improvements or innovations in the financing and delivery of health care services, as demonstrated by (i) the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services; (ii) the potential for provision of health care services on an outpatient basis; (iii) any cooperative efforts to meet regional health care needs; and (iv) at the discretion of the Commissioner, any other factors as may be appropriate; and

The proposed project will introduce cardiac catheterization services into the applicant's new Children's Tower. The concentration of pediatric health care services into a purpose built facility, on the same campus and connected to the medical center. Provision of pediatric care in a pediatric specific environment by an entire staff that specialize in pediatric care is expected to promote efficiency and quality care.

8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served, (i) the unique research, training, and clinical mission of the teaching hospital or medical school and (ii) any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care services for citizens of the Commonwealth, including indigent or underserved populations.

Regarding this consideration, the applicant explains:

VCUHS offers a broad range of pediatric- and adolescent-focused services across Central Virginia under the umbrella of VCUHS-CHoR. VCUHS-CHoR is committed to training future pediatric caregivers and conducting research that improves the understanding and treatment of childhood diseases. VCUHS-CHoR offers numerous unique multi-

disciplinary clinical programs and has established various new fellowship training programs for the next generation of clinicians to ensure that the needs of the community's children and their families are met. Housing pediatric-focused GPOs in pediatric-focused buildings will enable VCUHS to better educate learners and serve as a resource for pediatric clinical research in furtherance of its mission to the community. With more concentrated pediatric surgery volumes in a pediatric setting, there will be more opportunities for meaningful pediatric-focused education and research.

DCOPN Staff Findings and Conclusions

Virginia Commonwealth University Health System proposes to expand its existing cardiac catheterization service through the addition of one new cardiac catheterization laboratory. The projected capital cost of the proposed project total \$6,205,961, the entirety of which will be funded from a gift from the Children's Hospital Foundation and the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with the proposed project. While the capital costs for the Virginia Commonwealth University Health System project are high compared to other recent similar projects. The Pro Forma Income Statement provided by the applicant indicates that the proposed project would contribute to the overall profitability of Virginia Commonwealth University Health System's cardiac catheterization program both in the immediate and the long-term. The applicant has provided a projected opening date of June 30, 2023.

Virginia Commonwealth University Health System's four existing catheterization laboratories operated at 101.7% of the SMFP threshold for expansion in 2020. There is not a reasonable alternative to the proposed project. DCOPN concludes that the applicant has adequately demonstrated a unique institutional need for the requested additional cardiac catheterization laboratory at Virginia Commonwealth University Health System. Should the Commissioner approve the proposed project, it would be subject to the 1.3% system-wide charity care condition.

DCOPN Staff Recommendations

The Division of Certificate of Public Need recommends **conditional approval** of Virginia Commonwealth University Health System's request to add one cardiac catheterization laboratory for the following reasons:

1. The proposed project is generally consistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.
2. The capital costs are reasonable.
3. The proposed project appears economically viable both in the immediate and in the long-term.
4. No reasonable alternatives to the proposed project exist.
5. The applicant has adequately demonstrated a unique institutional need for the additional cardiac catheterization lab.

6. There is no known opposition to the proposed project.
7. Approval of the proposed project is not likely to have a significant negative impact on the staffing or utilization of existing PD 15 providers of cardiac catheterization services.

DCOPN's recommendation is contingent upon Virginia Commonwealth University Health System's agreement to the following charity care condition:

Virginia Commonwealth University Health System will provide cardiac catheterization services to all persons in need of this service, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and facilitate the development and operation of primary care services to medically underserved persons in an aggregate amount equal to at least 1.3% of Virginia Commonwealth University Health System's total patient services revenue derived from cardiac catheterization services as valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. Compliance with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement. Spotsylvania Regional Medical Center, Inc. will accept a revised percentage based on the regional average after such time regional charity care data valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. is available from Virginia Health Information. The value of charity care provided to individuals pursuant to this condition shall be based on the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.

Virginia Commonwealth University Health System will provide cardiac catheterization services to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et seq. Additionally, Virginia Commonwealth University Health System will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.