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

Staff Analysis

May 19, 2022

COPN Request No. VA-8621
Reston Hospital Center, LLC
Reston, Virginia
Introduce open heart surgery

Applicant

Reston Hospital Center, LLC (RHC) is a limited liability company formed in 1999 under the laws of the State of Delaware. The ultimate corporate parent of RHC is HCA Healthcare, Inc. (HCA). RHC is located in Reston, Virginia, which is located in Planning District (PD) 8, Health Planning Region (HPR) II.

Background

RHC is a 231-bed acute care hospital that provides a variety of services including cardiology, oncology, orthopedics, pediatrics, neonatal care, diagnostic imaging, and emergency services. On June 30, 1998, the State Health Commissioner (Commissioner) issued COPN No. VA- 02091 authorizing HCA Health Services- Reston Hospital Center to establish cardiac catheterization services with one cardiac catheterization lab. On January 8, 2016, the Commissioner issued COPN No. VA-04499 authorizing the increase in the number of cardiac catheterization labs from one to two. There are currently two providers of open heart surgery in PD 8, Inova Fairfax Hospital and Virginia Hospital Center.

Proposed Project

RHC proposes to introduce open heart surgery. The project would not require any new construction, as RHC intends to convert an existing general OR to a cardiac surgery OR. Approval of the proposed project would increase the total number of open heart surgical programs in PD 8 from the current two programs to three. The total capital and financing costs for the project are $2,551,930 (**Table 1**). The project will be funded through the internal resources of HCA.

Table 1. Capital and Financing Costs

Equipment Not Included in Construction Contract	$2,551,930
TOTAL Capital and Financing Costs	**$2,551,930**

Source: COPN Request No. VA-8621

Project Definitions

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the "[i]ntroduction into an existing medical care facility described in subsection A of…open heart surgery…when such medical care facility has not provided such service in the previous 12 month." A medical care facility includes "[a]ny 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;**

RHC proposes to introduce open heart surgery. The project would not require any new construction, as RHC intends to convert an existing general OR to a cardiac surgery OR. There are two existing providers of open heart surgical services in PD 8. The applicant asserts that existing providers are not reasonably accessible to western PD 8, and the approval of open heart surgery would improve access to patients in western Fairfax County, Loudon County, and other high population and rapidly growing communities in the western portion of the planning district. Opposing parties, discussed in detail below, assert that the planning district is well served with regards to open heart surgical services. As discussed in 12VAC5-230-440 below, this is correct in terms of the one-hour one way travel time discussed in that section. However, looking at **Figure 1** below, DCOPN notes that open heart surgical services are clearly located solely in the eastern section of the PD. DCOPN has traditionally put some weight on reduced travel time when it is significant, as it is here. This is because significant travel time can lead to delays in treatment, increased time away from work for appointments, and other issues. One letter of opposition states that RHC is less than 25 minutes from the two existing providers. DCOPN notes that, at non-peak travel times, mapping software shows a shortest travel time of 24-25 minutes. However, avoiding toll roads that may not be chosen by lower income patients, this travel time jumps to approximately 37 minutes for each location. While not sufficient to necessitate approval absent meeting other significant criteria, such as a showing of sufficient volume and lack of harm to existing providers, there is definite benefit to expanding the available open heart surgical services beyond the eastern part of the state.

Geographically, RHC is located less than one mile from VA SR 267, three miles from VA SR 7, and abuts VA SR 286. Public transport to the facility is readily available. Public bus transportation is available through the Fairfax Connecter, which also provides connections to the Metrobus for wider geographic coverage, and metro rail is available at the Wiehle-Reston East Station, roughly two miles from RHC, with the Reston Town Center Station, approximately one mile from RHC, expected to open in 2022.

RHC argues that the American College of Surgeons states that Level II trauma centers should provide cardiac surgery, and that Reston is the only Level I or Level II trauma center in Virginia that does not offer open heart surgery. RHC's status as a Level II trauma center, however, is optional, and is not conditioned on their ability to establish open heart surgery. Opposing parties state that approval of open heart surgical services based on a Level II trauma center designation would set a bad precedent that would lead to the proliferation of open heart surgical programs, despite the lack of sufficient volume, as more facilities acquire this designation. DCOPN agrees with the opposing parties' assertions, and rejects RHC's arguments regarding the necessity of open heart surgical services at Level II trauma centers.

As depicted in **Table 3**, at an average annual growth rate of 1.28%, PD 8's population growth rate is higher than the state's average annual growth rate of 0.76%. Overall, the planning district is projected to add an estimated 350,128 people in the 10-year period ending in 2030—an increase of approximately 35,013 people annually. Most of the population increase in PD 8 is attributed to Fairfax County, Prince William County, and Loudoun County. Fairfax County, where RHC is located, has the second lowest average annual change for this time period. Despite this, Fairfax County has the largest population in the planning district, and is projected to retain this status through 2030. Moreover, it is projected to increase its population by 81,521, the third largest increase in population in the planning district.

Regarding residents 65+ and older, as depicted in **Table 4**, at an average annual growth rate of 3.24%, PD 8's population growth rate is higher than the state's average annual growth rate of 2.45%. Overall, the planning district is projected to add an estimated 112,778 people in the 10-year period ending in 2030—an increase of approximately 11,278 people annually. Most of the ages 65+ population cohort increase in PD 8 is attributed to Fairfax City, Fairfax County, and Arlington County. Fairfax County, where RHC is located, has the third highest average annual change for this time period with this population cohort. Additionally, Fairfax County currently has the second largest population in the planning district for this population cohort, but is expected to relinquish this ranking to Fairfax City and fall to third largest by 2030. Finally, Fairfax County is projected to increase its population by 28,132, the third largest increase in population in the planning district for the 65+ population cohort.

DCOPN is not aware of any other geographic, socioeconomic, cultural, or transportation barriers to access to care that are not addressed elsewhere in this report.

Table 2. Population Projections for PD 8, 2020-2030

Locality	2020	2030	% change	Avg Ann % Chg
Alexandria City	166,261	182,067	9.51%	0.91%
Arlington County	249,298	274,339	10.04%	0.96%
Fairfax City	25,047	26,397	5.39%	0.53%
Fairfax County	1,162,504	1,244,025	7.01%	0.68%
Falls Church City	14,988	17,032	13.64%	1.29%
Loudoun County	430,584	554,808	28.85%	2.57%
Manassas City	43,099	46,332	7.50%	0.73%
Manassas Park City	17,086	20,284	18.72%	1.73%
Prince William County	478,134	571,844	19.60%	1.81%
Total PD 8	**2,587,000**	**2,937,128**	**13.53%**	**1.28%**
Virginia	8,655,021	9,331,666	7.82%	0.76%

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

Table 3. Population Projections for PD 8, 2020-2030: Age 65+

Locality	2020	2030	% change	Avg Ann % Chg
Alexandria City	22,515	26,951	19.70%	1.81%
Arlington County	151,585	184,218	21.53%	1.97%
Fairfax City	45,314	84,522	86.52%	6.43%
Fairfax County	52,698	80,830	53.38%	4.37%
Falls Church City	17,359	22,175	27.74%	2.48%
Loudoun County	3,754	4,611	22.82%	2.08%
Manassas City	1,908	2,317	21.47%	1.96%
Manassas Park City	3,930	5,387	37.05%	3.20%
Prince William County	1,426	2,258	58.35%	4.70%
Total PD 8	**300,491**	**413,269**	**37.53%**	**3.24%**
Virginia	1,352,448	1,723,382	27.43%	2.45%

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

2. The extent to which the proposed project will meet the needs of 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;

Letters of Support
DCOPN received 12 letters of support from the following individuals:

- Virginia Delegate Kenneth R. Plum
- The Regional Vice President of Anthem Health Plans of Virginia, Inc. (Dup)
- The President of the Greater Reston Chamber of Commerce.
- 7 physicians and other medical professional affiliated with RHC.
- 2 physicians not identifiably affiliated with RHC.

Collectively, these letters discuss the benefits of introducing a new open heart surgical service located in the western part of the planning district. Additionally, the letters allege a

significant growth in cases in the planning district. These assertions will be addressed in the relevant sections of this report.

Letters of Opposition

DCOPN received eight letters of opposition from Virginia Hospital Center (VHC), Inova Health System (Inova), and six physicians.

The physician letters present several different arguments. First, the letters discuss the investment of time and resources required to build a high quality cardiac surgery team. RHC has stated that the delay of 2.5 years between approval and the commencement of open heart services would be to, in part, provide "ample time to assemble an outstanding team of highly-qualified professional to staff the open heart surgery program." As such, DCOPN concludes that this concern has been sufficiently addressed by the applicant. They additionally state that creating such a team would be almost impossible with the volumes projected by RHC. The ability of RHC to meet certain volume thresholds will be discussed in the relevant sections below. Next, the letters object to RHC's argument that the open heart program is necessary because of its level II trauma designation. As discussed above, DCOPN agrees that this argument is not persuasive. These letters additionally assert that the RHC program will be low volume and have a negative effect on existing providers. These assertions will be addressed in the relevant sections below.

The final physician, Dr. Speir, who is the Medical Director of Cardiac Surgical Services for Inova, provided a significantly longer and more detailed letter addressing several objections to the proposed project. Dr. Speir first discusses the correlation between volume and quality in cardiac surgery. Dr. Speir next discussed RHC's definition of procedures. Dr. Speir finally asserts that RHC will divert patients from other open heart programs based on the growth of TAVR but not CABG over the past several years. As all of these factors are fundamental to sections of the SMFP, they are addressed in the relevant sections below.

Inova, in its letter of opposition, first states that nothing has changed since the denial of COPN Request No. VA-8436 in 2020. Inova then addresses the question of if volumes are increasing in PD 8, and disagrees with the applicant's assertion that they are. Inova next asserts that the requests by the applicant for open heart surgical services have varied significantly between applications and discusses their use of cases and billing codes. Inova next asserts that the projected volumes by Reston would be unachievable. Next, Inova asserts that RHC's program would have a substantial negative impact on Inova and VHC's open heart programs. DCOPN will address any allegations made regarding the impact on VHC elsewhere, but it finds Inova's assertion regarding its own program suspect. In the staff report for COPN Request No. VA-8436, DCOPN noted that Inova's open heart program at Inova Fairfax Hospital was the busiest open heart surgical program in the Commonwealth based on available VHI data. As such, DCOPN finds it difficult to believe that RHC's program, which Inova alleges would be low volume, would materially affect the cardiac program that was, as of last evaluation approximately two years ago, the busiest in the Commonwealth. To do otherwise would effectively state that any level of patient loss by a cardiac program is sufficient to affect materially an existing provider, which would

effectively bar the establishment of any new cardiac program. Finally, Inova asserts that Reston's Level II trauma surgery designation does not justify the need for open heart surgical services. As discussed previously, DCOPN agrees with this assertion.

VHC, in its letter of opposition, states first that there is not a need in the planning district for RHC's open heart surgical program. In support of this, the applicant cites two prior decisions detailed in section 2.v below. As the determination of public need for the proposed project is the sole focus of DCOPN's staff report, this determination will be discussed throughout the report. VHC additionally states that the proposed project will not increase geographic or financial access to open heart surgical services. Based on **Figure 1**, were coverage alone sufficient to find that a need does not exist in the planning district, one open heart program would be sufficient for this planning district. This is clearly not the case, nor would VHC, as the lower volume open heart program in the planning district, be arguing this point. As such, DCOPN does not accept this argument as a reason, on its own, to reject the proposed project. Finally, VHC asserts that RHC would have a detrimental effect on utilization at VHC. DCOPN will address this assertion in the relevant section below.

Public Hearing

DCOPN provided notice to the public regarding this project on March 10, 2022. The public comment period closed on April 25, 2022. On May 9, 2022, the Health Systems Agency of Northern Virginia (HSANV) held a public hearing for the proposed project. The proposed project was presented by one representative. Six individuals spoke in opposition of the proposed project. Two of these individuals represented the two health systems that wrote letters opposing the project. Three of the remaining individuals had previously submitted letters of opposition to the proposed project. The final individual, who was affiliated with Inova, discussed anticipated patient volumes and potential issues that would result from this. These points mirror points made by other opposing parties, and are discussed where relevant in this report.

(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 proposed project is more beneficial than the alternative of the status quo. As discussed above, while open heart surgical services are sufficient in the planning district to meet the one-hour travel time one way mandated in 12VAC5-230-440, **Figure 1** clearly shows that the distribution of open heart surgical services is currently located solely within the eastern portion of the planning district. As discussed above, DCOPN has traditionally put some weight on reduced travel time when it is significant, as it is here. This is because significant travel time can lead to delays in treatment, increased time away from work for appointments, and other issues. Such findings of benefit are predicated on there being sufficient volume to justify the service, and to find that the proposed project would not materially detrimentally affect existing providers. As discussed in 12VAC5-230-450 below, objective data and evidence presented by the applicant and opposing parties is sufficient to determine that sufficient volume exists to justify this new service, and to find that the proposed project would not materially detrimentally affect existing providers. Based on these factors, DCOPN concludes that the proposed project would increase

access to open heart surgical services by decreasing travel time by a significant amount for residents of the western portion of the planning district. As such, DCOPN concludes that the proposed project is more beneficial than the alternative of the status quo.

(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;

At its May 9, 2022 meeting, the HSANV Board of Directors reviewed the COPN application filed by Reston Hospital Center (COPN Request VA-8621) seeking authorization to establish an open heart surgery service. The board voted eleven in favor and two opposed to recommend that the application be denied.

The board bases the recommendation on its review of the application, on the HSANV staff report on the proposal, on the information presented at the May 9, 2022 meeting held on the application, and on several findings and conclusions, including:

1. There is no reliable evidence of a public need for an additional open heart surgery program or for additional open heart surgery capacity in Northern Virginia (PD 8). The project is not consistent with the public need planning requirements of the Virginia State Medical Facilities Plan (SMFP), notably Subsection 12VAC5-230-450.A.3.

2. RHC's interpretation of longstanding demand and capacity planning metrics specified in the Virginia SMFP is problematic. Its reliance on overly broad facility data rather than discrete population based data and analyses is limiting, unpersuasive and misleading.

3. There is no evidence of unmet need or suppressed demand for open heart surgery or other specialized cardiovascular care in the planning region. Low endemic cardiovascular use rates, and comparative low service volumes, are not indicative of a need for additional services or capacity.

4. Existing open heart surgery programs have served the region well for decades and can continue to do so indefinitely. Existing services offer quality, convenient care with average charges much lower than the statewide average and less than half of charges at RHC's sister Virginia hospitals with open heart surgery programs.

5. An unneeded, duplicative open heart surgery program would affect service volumes at existing services. If Reston Hospital Center were to achieve the large surgery caseloads projected, service volume reductions at existing services would be substantial.

6. Existing service providers oppose the project. Both argue that there are substantial clinical and economic risks associated with establishing an unwarranted low volume, high cost open heart surgery programs.

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

The total capital and financing cost for the project is $2,551,930 (**Table 1**), which would be funded through the internal resources of HCA. The costs for the project are reasonable, and less expensive than previously approved projects to add open heart services. For example, COPN VA-03984 issued to Rockingham Memorial Hospital to introduce open heart surgery services, which cost approximately $2,995,189; and COPN VA- 03722 issued to Maryview Medical Center to introduce open heart surgery services, which cost approximately $6,263,582. In both cases, the difference in cost is a result of the construction costs associated with the project. The costs outside of these remain relatively consistent amongst the three projects. As discussed above, the proposed project would increase access to open heart surgical services by decreasing travel time by a significant amount for residents of the western portion of the planning district without detrimentally affecting the utilization of existing providers.

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

As **Table 4** below demonstrates, RHC provided 1.3% of its gross patient revenue in the form of charity care in 2020. This percentage is the second lowest in HPR II in 2020, and less than half the average of the 3.4% hospital-wide charity care percentage provided by all reporting acute care hospitals. In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project be approved, RHC is expected to provide a level of charity care for total gross patient revenues derived from its COPN authorized services that is no less than the equivalent average for charity care contributions in HPR II.

Table 4: HPR II 2020 Charity Care Contributions

Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Inova Alexandria Hospital	$949,158,182	$57,879,875	6.1%
Inova Mount Vernon Hospital	$499,398,426	$29,342,493	5.88%
Inova Loudoun Hospital	$817,869,692	$35,123,877	4.29%
Novant Health UVA Health System Prince William Medical Center	$530,326,336	$21,923,014	4.13%
Inova Fairfax Hospital	$3,855,962,450	$147,813,100	3.83%
Sentara Northern Virginia Medical Center	$823,831,674	$29,925,512	3.63%
Inova Fair Oaks Hospital	$649,476,560	$21,302,369	3.28%
Virginia Hospital Center	$1,491,327,243	$29,205,595	1.96%
Novant Health UVA Health System Haymarket Medical Center	$284,391,247	$4,747,340	1.67%
Reston Hospital Center	$1,535,959,085	$19,925,030	1.3%
StoneSprings Hospital Center	$247,806,370	$1,302,439	0.53%
Total $ & Mean %	**$11,685,507,265**	**$398,490,644**	**3.4%**

Source: Virginia Health Information

(vi) at the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a proposed project.

On August 1, 2017, RHC submitted an application for COPN Request No. VA-8306, which proposed to introduce open heart surgery at RHC by renovating two existing operating rooms for open heart surgery cases. On November 13, 2017, HSANV's recommendation of denial of VA-8306 passed by a vote of twelve in favor and five opposed. On November 29, 2017, DCOPN issued a staff report recommending denial of VA-8306. On December 14, 2018, following an informal fact finding conference, the Commissioner adopted the adjudication officer's recommendation to deny RHC's project. On January 29, 2019, RHC submitted an application for COPN Request No. VA-8436, which proposed to introduce open heart surgery at RHC by renovating one existing operating room for open heart surgery cases and converting an adjacent office to a pump room. On May 22, 2019, HSANV's recommendation of denial of VA-8436 passed by a voted seven in favor and four opposed. On May 30, 2019, DCOPN issued a staff report recommending denial of VA-8436. On February 25, 2020, following an informal fact finding conference, the Commissioner adopted the adjudication officer's decision to deny RHC's project.

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

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 project with the predecessor of the SHSP, the SMFP.

The State Medical Facilities Plan (SMFP) contains criteria/standards for the establishment of open heart surgery services. They are as follows:

Part IV Cardiac Services
Article 2
Criteria and Standards for Open Heart Surgery

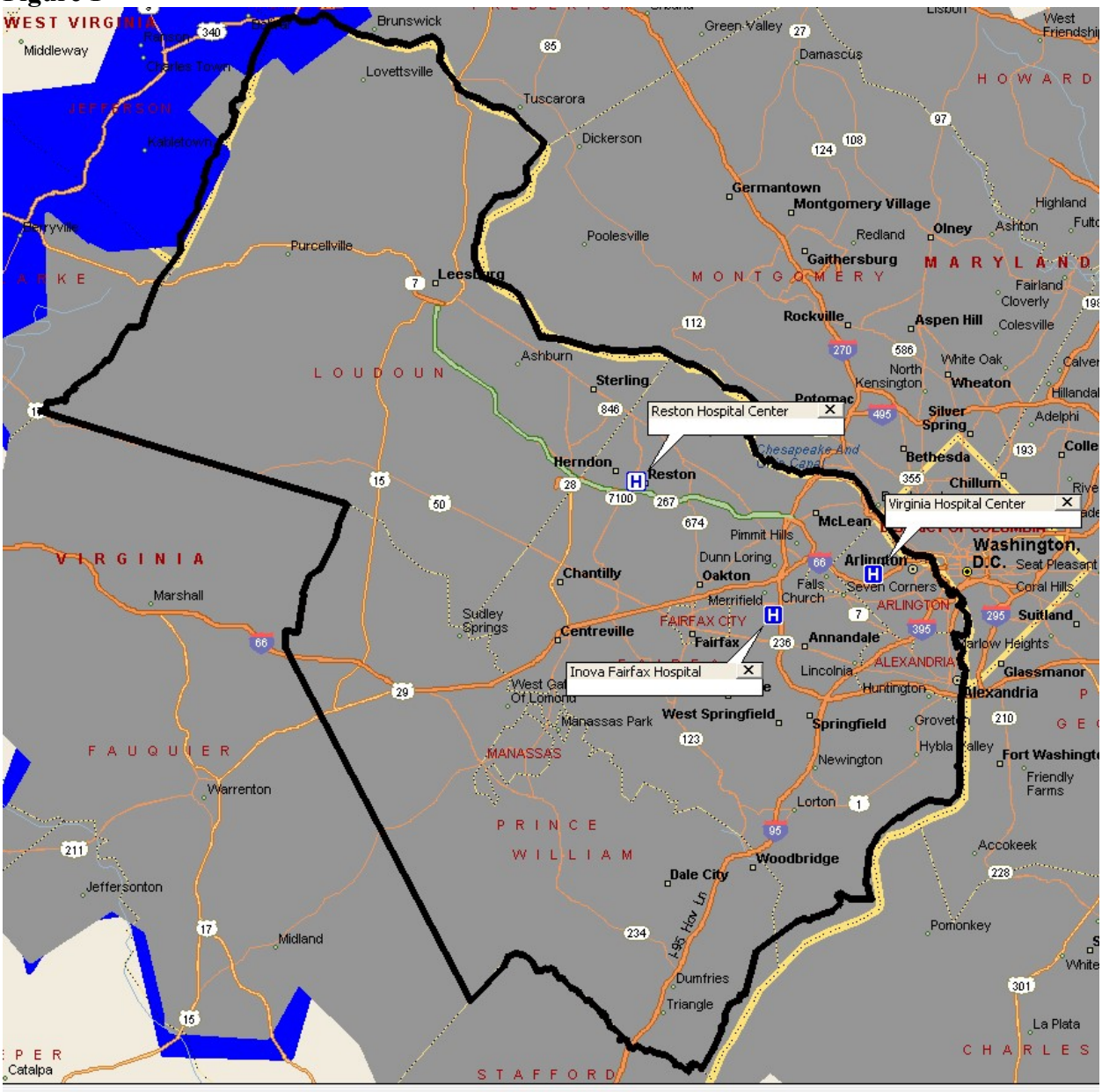
12VAC5-230-440. Travel time.

A. Open heart surgery 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** is the boundary of PD 8. The grey shaded area includes all locations that are within 60 minutes driving time one way under normal conditions of existing open heart surgical services in PD 8. The blue shaded area includes all locations that are within 60 minutes driving time one way under normal conditions of the proposed new service that are not currently within 60 minutes driving time of existing open heart surgical services. **Figure 1** clearly illustrates that open heart surgical services are already well within a one-hour drive under

normal conditions for nearly all residents of the planning district. Traffic congestion, however, is a regular complaint of those attempting to navigate the major travel arteries of PD 8. As the proposed project would be located in a facility that does not already have open heart surgery capability, it would have some positive impact on geographical access to this service in PD 8.

Figure 1



B. Such services shall be available 24 hours a day, seven days a week.

The applicant provided assurances that the service will be available 24 hours a day, seven days a week.

12VAC5-230-450. Need for new service.

A. No new open heart services should be approved unless:

1. The service will be available in an inpatient hospital with an established cardiac catheterization service that has performed an average of 1,200 DEPs for the relevant reporting period and has been in operation for at least 30 months;

There has been some disagreement in recent applications about whether the use of "an average of" in this section of the SMFP should be read to be 1,200 DEPs per facility for the relevant reporting period, or per cardiac catheterization service for the relevant reporting period. The Fourth Circuit Court of Virginia[1] and the Fourth Circuit Appellate Court of Virginia[2] upheld the Commissioner's interpretation that this section should be read to be evaluated per cardiac catheterization lab. As such, DCOPN adopts this interpretation for its review of this project.

Table 5 below shows the cardiac catheterization diagnostic equivalent procedures for CRMC in 2016 through 2020. Averaging the total number of annual DEPs per year per cardiac catheterization lab, Reston reached an average 1,312 DEPs per year per lab in the past 30 months for which DCOPN has data available from VHI, or 109.3% of the required standard. As such, DCOPN concludes that the applicant has satisfied this standard.

Table 5. Adult Cardiac Catheterization Utilization (in DEPs) at RHC, 2015-2019

	Cardiac Cath Labs	Diagnostic	Therapeutic	Same Session	Total DEPs[3]	DEPs per Lab	Utilization Rate
2016	1	264	151	220	1226	1,391	102.2%
2017	1	393	145	236	1391	1,399	115.9%
2018	1	368	184	221	1399	1,588	116.6%
2019	1	363	203	273	1588	1,556	132.3%
2020	2	439	197	241	1556	627	52.2%
Average						1,312	109.3%

Source: VHI

2. Open heart surgery services located in the health planning district performed an average of 400 open heart and closed heart surgical procedures for the relevant reporting period; and

In recent COPN applications for open-heart surgery, there has been some discussion regarding the interpretation of this section of the SMFP[4]. First, there has been some contention regarding whether this section mandates procedures per operating room or

[1] Chesapeake Hospital Authority d/b/a Chesapeake General Hospital v. State Health Commissioner, et. al. (Civil Docket No. CL18-6997).
[2] Chesapeake Hospital Authority d/b/a Chesapeake General Hospital v. State Health Commissioner And Sentara Hospitals (Record No. 0116-20-1).
[3] DEPs are calculated as follows: "A diagnostic procedure equals 1 DEP, a therapeutic procedure equals 2 DEPs, a same session procedure (diagnostic and therapeutic) equals 3 DEPs…" (12VAC5-230-10).
[4] COPN Request Nos. VA-8300, VA-8306, & 8436.

procedures per open heart surgical program. The Commissioner, in denying COPN Request No. VA-8300, clearly determined that "services" should be interpreted to mean per operating room[5]. DCOPN, in past reviews, has viewed the Commissioner's decision as instructive[6]. A recent decision by the Fourth Circuit Court of Virginia, however, determined that this section should be read to be evaluated by open heart surgical program[7]. DCOPN adopts this interpretation for its review of this project.

There has additionally been some discussion regarding the interpretation of the term "procedures" in RHC's last request to add open heart surgical services. The applicant here once more asserts that the term "procedure" should be read as each ICD-9 or ICD-10 code that meets the definition of open heart surgery performed on a patient during surgery. 12VAC5-230-10 defines a procedure as "…a study or treatment or a combination of studies and treatments identified by a distinct ICD-9 or CPT code performed in a single session on a single patient." Letters of opposition submitted by individuals associated with Inova Health System assert that the proper interpretation of "procedure" should be cases rather than distinct ICD-9 or ICD-10 codes. DCOPN's report found that the applicant did not meet this standard under either interpretation, and did not, therefore, take a position on the interpretation of "procedure." The Adjudication Officer's report adopts Inova's interpretation of the term "procedure." This interpretation was adopted by the Commissioner in his denial of the project. As such, DCOPN is bound to this interpretation of the term "procedure," but asks the Commissioner, in their review of this staff report, to reconsider this interpretation as it runs counter to the plain language of 12VAC5-230-10.

DCOPN notes that its finding that the applicant was not consistent under either definition of "procedure" was a result of the 'per operating room" interpretation of this section. Under the "per open heart surgical program" interpretation, RHC would have been consistent with this section.

Table 6 below shows the adult open-heart surgery volume for PD 8 in 2020, the most recent year for which data has been made available by VHI. In 2020, an average of 889.5 open-heart and closed-heart surgical procedures were performed in the health planning district. As such, DCOPN concludes that the applicant has satisfied this standard.

[5] Adjudication Officer's Report, COPN Request No. VA-8300 (Adopted by the Commissioner on August 24, 2018).
[6] COPN Request No. VA-8436.
[7] Chesapeake Hospital Authority d/b/a Chesapeake General Hospital v. State Health Commissioner et. al. (Civil Docket No. CL18-6997).

Table 6. PD 8 2020 Adult Open Heart Surgery Volume (Cases)

Facility	Open & Closed Heart Surgery Volume
Inova Fairfax Hospital	1,127
Virginia Hospital Center	652
Total	**1,779**
Average	**889.5**

Source: VHI

3. The proposed new service will perform at least 150 procedures per room in the first year of operation and 250 procedures per room in the second year of operation without significantly reducing the utilization of existing open heart surgery services in the health planning district.

The applicant projects 419 procedures in the first year and 671 procedures in the second year. In the letters of opposition, assertions are made that these projections are unsubstantiated. While DCOPN agrees that the data provided by the applicant is not as robust as it would prefer, it finds that the information is sufficient to support the assertions made by the applicant. DCOPN notes that this predication is under the applicant's interpretation of procedures, each ICD-9 or ICD-10 billing code, rather than the Commissioner's traditionally held interpretation of procedures, cases. Inova, in their letter of opposition, approximates 2.0 ICD-10 billing codes on average per case in order to convert RHC's projections to cases. Using Inova's proposed conversion table, this would amount to 209.5 procedures in the first year and 335.5 procedures in year two. Both of these projected procedure numbers exceed the necessary thresholds for this section.

The applicant states that "while older studies suggest that there is not a correlation between open heart volumes and outcomes, more recent studies have concluded that this is not the case." While Reston is factually correct that the studies that it cites are more recent than one of the studies that shows the correlation between volumes and outcomes[8], it ignores the fact that one study, newer than their cited studies, reaffirms this correlation[9]. Moreover, RHC is aware of this study, as it was discussed during DCOPN's review of COPN Request No. VA-8436. Finally, RHC is well aware that this issue has already been addressed before the Commissioner as recently as two years ago, and the Commissioner, weighing all evidence, continued to uphold the correlation between volume and better surgical outcomes. As RHC is not presenting any new information that has not already been addressed previously by the Commissioner, it is unclear why they continue to make this argument.

Both Inova and VHC assert that approval of the proposed project would harm their open heart surgical programs. Inova and Dr. Speir argue that open heart volumes are not growing. In support of this, they assert that open heart volume is flat with the exception of TAVR, which would not be performed by a new open heart program for at least its first two years. Inova argues, as a result, that these procedures must be removed from consideration. As

[8] Peterson, E, Coombs, L, DeLong, E, et al. Procedural Volume as a Marker of Quality for CABG Surgery. The Journal of the American Medical Association. 2004; 291(2): 195-201. doi: 10.1001/jama.291.2.195.
[9] Vemulapalli, S, Carroll, J, Mack, M, et al. Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. The New England Journal of Medicine. 2019; doi: 10.1056/NEJMsa1901109.

TAVR has become, in Dr. Speir's own words, the accepted standard of care, it is unsurprising that this method would be increasing in volume while others remained stagnant. While DCOPN has, in the past, separated TAVR and CABG in analyzing growth in the planning district, the trend towards TAVR requires that this method be reevaluated. If TAVR is not able to be performed initially by new open heart surgical services, but it is an established standard of care, exclusion of the continued growth of TAVR would likely result in the complete inability of new providers to establish cardiac services in a clearly growing market. Where need and a growing patient base clearly exists, it does not behoove the Commonwealth to uphold a policy not mandated by the SMFP that prevents the establishment of new providers to better distribute necessary services throughout the planning district.

VHC states in its letter of opposition that RHC is less than 25 minutes from Inova Fairfax Hospital and VHC. DCOPN notes that, at non-peak times, mapping software shows a shortest travel time of 24-25 minutes. However, avoiding toll roads that may not be chosen by lower income patients, this travel time jumps to approximately 37 minutes for each location. VHC additionally states that VHC's primary service area overlaps with RHC's primary service area. Finally, VHC states that diversion of patients would be particularly significant for VHC because it has historically hovered below the 400-procedure threshold. DOCPN notes that the 2020 VHI Data (**Table 6**) shows VHC as performing 652 procedures during that year.

VHC and Inova both cite prior decisions stating that RHC's program would harm existing providers. These determinations were made using older data and excluding TAVR. To consider determinations made on outdated data binding, when new data exists, runs contrary to both COPN precedent and common sense and, as previously mentioned, would effectively bar entry into the market of any new providers. As such, DCOPN rejects these arguments. Both VHC and Inova argue that the report provided by RHC is overly broad and inflates case numbers. While DCOPN does not agree with this assertion, there is another set of data, provided by one of the opposing parties, that would reach a similar determination with less contention regarding the validity of the data.

Looking at the annualized data provided by Inova in its letter of opposition, DCOPN notes that Inova's predicted procedures for 2021 have grown substantially since the pre-pandemic numbers of 2018 and 2019. Inova's procedure count shows an increase of 157 cases from 2019 and 345 cases from 2018. This growth is nearly sufficient for a new open heart surgical program to nearly reach the 400 procedure threshold indicated by the SMFP. DCOPN acknowledges that the number provided by Inova includes pediatric open heart surgeries and heart transplant cases in addition to TAVR, so reliance on them is tenuous. Nonetheless, DCOPN considers these volumes sufficient to show a continued growth of the service in the planning district. Based on this level of growth, DCOPN concludes that sufficient open heart volume exists to accommodate RHC's projected volumes without significantly reducing the utilization of the two existing providers.

For the reasons discussed above, DCOPN concludes that the applicant is consistent with this section.

B. Preference may be given to a project that locates new open heart surgery services at an inpatient hospital more than 60 minutes driving time one way under normal condition from any site in which open heart surgery services are currently available and:

1. **The proposed new service will perform an average of 150 open heart procedures in the first year of operation and 200 procedures in the second year of operation without significantly reducing the utilization of existing open heart surgery rooms within two hours driving time one way under normal conditions from the proposed new service location below 400 procedures per room; and**
2. **The hospital provided an average of 1,200 cardiac catheterization DEPs during the relevant reporting period in a service that has been in operation at least 30 months.**

Not applicable. The proposed project is located within 60 minutes driving time one way under normal condition from a site in which open heart surgery services are currently available.

12VAC5-230-460. Expansion of service.
Proposals to expand open heart surgery services shall demonstrate that existing open heart surgery rooms operated by the applicant have performed an average of:

1. **400 adult equivalent open heart surgery procedures in the relevant reporting period if the proposed increase is within one hour driving time one way under normal conditions of an existing open heart surgery service; or**
2. **300 adult equivalent open heart surgery procedures in the relevant reporting period if the proposed service is in excess of one hour driving time one way under normal conditions of an existing open heart surgery service in the health planning district.**

Not applicable. The proposed project is seeking to establish a new open heart service rather than expand an existing open heart service.

12VAC5-230-470. Pediatric open heart surgery services.
No new pediatric open heart surgery service should be approved unless the proposed new service is provided at an inpatient hospital that:

1. **Has pediatric cardiac catheterization services that have been in operation for 30 months and have performed an average of 200 pediatric cardiac catheterization procedures for the relevant reporting period; and**
2. **Has pediatric intensive care services and provides specialty or subspecialty neonatal special care.**

Not applicable. The applicant is not proposing to establish pediatric open heart surgery services.

12VAC5-230-480. Staffing.

A. Open heart surgery services should have a medical director who is board certified in cardiovascular or cardiothoracic surgery by the appropriate board of the American Board of Medical Specialists.

The applicant provided assurances that open heart surgery services will be under the direction of a qualified medical director.

In the case of pediatric cardiac surgery, the medical director should be board certified in cardiovascular or cardiothoracic surgery, with special qualifications and experience in pediatric cardiac surgery and congenital heart disease, by the appropriate board of the American Board of Medical Specialists.

Not applicable. The applicant is not proposing to establish pediatric open heart surgery services.

B. Cardiac surgery should be under the direct supervision of one or more qualified physicians.

The applicant provided assurances that cardiac surgery services will be under the direct supervision of one or more qualified physicians.

Pediatric cardiac surgery services should be under the direct supervision of one or more qualified physicians.

Not applicable. The applicant is not proposing to establish pediatric open heart surgery services.

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;

Given that HCA, the applicant's health system, does not perform open heart surgery within PD 8, approval of the proposed project would foster institutional competition. However, with open heart surgical programs, institutional competition is not always beneficial because of the correlation between volumes and outcomes that has long been recognized by the Commissioner. As discussed above, in this case, the data, both in terms of volumes of existing providers and growth of cases, does not support the argument that the addition of the RHC open heart surgical program would be detrimental of existing providers. While access is discussed elsewhere in the report, DCOPN is unable to address it here as the applicant does not make any substantive arguments regarding beneficial competition. While the benefits of the fostered institutional competition are unable to be determined with the data presented by the applicant, DCOPN is able to ultimately conclude that the competition would not be materially detrimental to existing providers.

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;

As discussed throughout this report, the two existing providers of open heart surgical services allege that the proposed project would detrimentally affect the utilization and efficiency of their services and, as a result, potentially put patients in PD 8 at risk. DCOPN analysis of both current volumes and open heart surgical growth does not support the assertion that the addition of open heart surgical services at RHC would materially impact the existing open heart surgical programs. As such, DCOPN concludes that the proposed project would not materially detrimentally affect the utilization and efficiency of the two existing providers in PD 8.

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 Pro Forma Income Statement (**Table 7**) provided by the applicant projects a net profit of $951,457 by the end of the first year of operation and a net profit of $1,691,300 by the end of year two for the proposed project. The total capital and financing cost of the proposed project is $2,551,930 (**Table 1**). All costs for the proposed project are attributed to equipment costs. The applicant states that the proposed project would be funded entirely through the internal resources of HCA. Accordingly, there are no financing costs associated with the proposed project. Analysis of the financial documents provided with the application show that this method of funding for the proposed project is viable. The applicant additionally asserts that they do not anticipate that the proposed project will not adversely affect the costs of providing care in the facility. As such, DCOPN concludes that the proposed project is feasible with regard to financial costs in both the immediate and the long-term.

With regard to staffing, the applicant anticipates a need for 12.4 FTEs, including 7 FTEs for Registered Nurses and 1.5 FTEs for nursing orderlies and attendants. The applicant asserts that the proposed project is not anticipated to have any impact on the staffing of other facilities in the service area. The applicant discusses many of the programs and benefits provided by HCA. The applicant provided several specific recruitment methods utilized to recruit nurses for this project, as well as those existing nursing vacancies at RHC. Moreover, part of the delay of approximately 2.5 years between approval of the project and the target date of opening on the open heart service, should this project receive approval, it is intended to give RHC sufficient time to assemble a team of highly-qualified professionals to staff the open heart program. The opposing parties make reference to potential impact on staffing at existing locations, but do so in a fashion so broad as to be applicable to any new open heart program. Objections that would effectively block any open heart program in the state, regardless of any other factors are, by their very nature, not reasonable. As the objecting parties have not provided specific verifiable evidence of how RHC specifically would impact their staffing, DCOPN cannot place substantive weight on these objections. As such, based on the information provided in both the application and supplemental responses, DCOPN finds that the RHC's efforts are sufficiently robust to conclude that the proposed project is feasible with regards to staffing, and is unlikely to adversely affect other providers in the area.

To briefly address HCA's objections regarding the questions about staffing, DCOPN must first clearly state that it is not holding, nor has it ever held, HCA to a more exacting and different

standard than Inova Health Systems. The comparison between the cited projects, COPN Request Nos. VA-8612 and 8613, and the proposed project, are inappropriate, as the staffing requirements differ greatly. While it is true that the staffing requirements for COPN Request Nos. VA-8612 and 8613 are significantly greater, they are not as specialized as those required in a project establishing open heart surgical services. In other recent open heart project requests[10], parties opposing the project alleged significant harm should even one employee be lost to the proposed project due to the extensive additional training required. In asking additional questions regarding staffing efforts, DCOPN is not seeking to hold HCA to a higher standard, but instead sought to allow the applicant additional opportunity to address an issue that is particularly contentious for this specific type of project.

Table 7. Pro Forma Income Statement

	Year 1	Year 2
Gross Revenue	$34,268,476	$56,035,028
Deductions from Revenue	$22,339,506	$36,529,048
Net Patient Services Revenue	**$11,928,970**	**$19,505,980**
Total Operating Expenses	**$10,977,513**	**$17,814,680**
Excess Revenue Over Expenses	**$951,457**	**$1,691,300**

Source: COPN Request No. VA-8621

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 proposal would introduce no new technology that would promote quality or cost effectiveness in the delivery of open heart surgery services. No improvements to the provision of health care services on an outpatient basis or cooperative efforts to meet regional health care needs were addressed by the applicant. DCOPN did not identify any other relevant factors to bring to the Commissioner's attention.

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.
(ii) Any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care for citizens of the Commonwealth, including indigent or underserved populations.

The project is not a 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.

[10] COPN Request No. VA-8427

DCOPN Findings and Conclusions

DCOPN finds that the proposed project to establish open heart surgery at RHC is consistent with the applicable criteria and standards of the SMFP and the eight Required Considerations of the Code of Virginia. Objective data and evidence presented by the applicant and opposing parties is sufficient to determine that sufficient volume exists to justify this new service and to find that the proposed project would not materially detrimentally affect existing providers. While HSANV voted eleven in favor and two opposed to recommend that the application be denied, its findings were predicated on the exclusion of TAVR from utilization trends. As TAVR is considered by many to be the standard of care with cardiac services, and its volume continues to rise, DCOPN concludes that its exclusion is no longer appropriate.

Additionally, DCOPN finds that the proposed project is preferable to the alternative of the status quo. While open heart surgery services are available within a sixty-minute drive, one-way, from over 95% of the population of PD 8, these services are geographically located solely in the eastern part of the state. DCOPN has traditionally put some weight on reduced travel time when it is significant, as it is here. This is because significant travel time can lead to delays in treatment, increased time away from work for appointments, and other issues. As sufficient volume to justify the new open heart surgical service exists in the planning district, the proposed project would significantly reduce the travel time of many residents of the western part of the planning district.

Finally, DCOPN finds that the total capital and financing cost for the project, $2,551,930, is reasonable (**Table 1**). The applicant states that the proposed project would be funded through the internal resources of HCA. The applicant additionally asserts that they do not anticipate that the proposed project will not adversely affect the costs of providing care in the facility. The costs for the project are reasonable and less expensive than previously approved projects to add open heart services. For example, COPN VA-03984 issued to Rockingham Memorial Hospital to introduce open heart surgery services, which cost approximately $2,995,189; and COPN VA- 03722 issued to Maryview Medical Center to introduce open heart surgery services, which cost approximately $6,263,582. In both cases, the difference in cost is a result of the construction costs associated with the project. The costs outside of these remain relatively consistent amongst the three projects.

DCOPN Staff Recommendations

The Division of Certificate of Public Need recommends the **conditional approval** of Reston Hospital Center, LLC's COPN Request No. VA-8621 to introduce open heart surgery at Reston Hospital. DCOPN's recommendation is based on the following findings.

1. The project is consistent with the applicable standards and criteria of the State Medical Facilities Plan and the eight Required Considerations of the Code of Virginia.

2. The growth in open heart surgical services in PD 8 is sufficient to support RHC's projected volumes without materially detrimentally effecting existing providers.

3. The project is preferable to the alternative of the status quo.

4. Proposed project is reasonable and less expensive than previously approved projects to add open heart services.

DCOPN's recommendation is contingent upon Reston Hospital Center, LLC's agreement to the following charity care condition:

Reston Hospital Center, LLC will provide open heart surgical 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 will facilitate the development and operation of primary medical care services to medically underserved persons in PD 8 in an aggregate amount equal to at least 3.4% of Reston Hospital Center, LLC's gross patient revenue derived from open heart surgical services. 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. Reston Hospital Center, LLC 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 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.

Reston Hospital Center, LLC will provide open heart surgical 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. Additionally Reston Hospital Center's will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.