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

Staff Analysis

November 21, 2022

COPN Request No. VA-8662
Chesapeake Hospital Authority d/b/a Chesapeake Regional Medical Center
Chesapeake, Virginia
Establish open-heart surgery services and convert one general purpose operating room to open-heart surgery

Applicant

Chesapeake Regional Medical Center (CRMC) is a general acute care hospital located in Chesapeake, Virginia. The Chesapeake Hospital Authority, chartered by an Act of the General Assembly in 1966, is the non-taxable parent company of CRMC. CRMC opened in 1976 and offers a comprehensive range of inpatient and outpatient healthcare services. Additionally, it is a joint owner of the Outer Banks Hospital, a critical access hospital located in Nags Head, North Carolina; 51% owner of Chesapeake Regional Surgery Center, Virginia Beach; and 91.6% owner of the Surgery Center of Chesapeake. CRMC's primary service area includes the city of Chesapeake, western Virginia Beach, and the northeastern North Carolina counties of Currituck, Camden, Dare and Pasquotank. CRMC is located in Planning District (PD) 20 within Health Planning Region (HPR) V.

Background

CRMC is a 310-bed, community-owned acute care hospital that has been in operation for forty-six years, and provides a variety of services, including obstetrics, oncology, radiation therapy, cardiac catheterization, diagnostic imaging, and has 13 general purpose operating rooms (ORs). CRMC has built its cardiovascular team and services specifically in response to demographic changes and its most recent Community Health Needs Assessment and has an "almost full line of cardiovascular services." CRMH's cardiovascular services have received recent recognition for quality in the areas of chest pain and stroke. An open-heart program has been part of CRMC's strategic plan for several years.

As demonstrated by Table 1, the adult cardiac surgical inventory of PD 20 consists of seven general use cardiac ORs and one OR used exclusively for adult cardiac surgery across three sites. Children's Hospital of The King's Daughters has a pediatric cardiac OR that has been excluded from this report.

Table 1. PD 20 COPN Authorized Adult Cardiac Surgery Operating Rooms: 2020

Facility	Operating Rooms	Exclusive Use Rooms	Total
Bon Secours Maryview Medical Center	2	0	2
Sentara Norfolk General Hospital	5	0	5
Sentara Virginia Beach General Hospital	0	1	1
Total	**7**	**1**	**8**

Source: Virginia Health Information ("VHI") 2020

Proposed Project

CRMC proposes to introduce open-heart surgery in newly-constructed space adjacent to its existing surgical suite, and close one existing general purpose OR, reassigning it to be used as the cardiac OR. Therefore the project is OR-inventory neutral. While the proposed project would not add an OR to the inventory in PD 20, it would increase the total number of open-heart surgical programs in PD 20 by one. The proposed designated OR would be utilized for open-heart, closed heart and other types of thoracic and vascular surgery. CRMC plans to add transcatheter aortic valve repair (TAVR) later. The total capital and financing costs for the project are $5,353,768 (Table 2) and would be paid for by the use of CRMC's accumulated reserves.

Table 2. Capital and Financing Costs

Direct Construction Costs	$412,920
Equipment Not Included in Construction Contract	$4,804,556
Architectural and Engineering Fees	$41,292
Other Consultant Fees	$95,000
TOTAL Capital and Financing Costs	**$5,353,768**

Source: COPN Request No. VA-8662

Project Definitions

Section 32.1 of the Code of Virginia defines a project, in part, as "Introduction into an existing medical care facility of any new… open heart surgery… which the facility has never provided or has not provided in the previous 12 months." A medical care facility includes "general hospitals…"

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 service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.**

   The applicant proposes to introduce open-heart surgery at CRMC by utilizing an operating room dedicated to cardiac surgery in newly-constructed space adjacent to existing surgical services. Currently, open-heart surgery exists at three locations in PD 20. In its application,

CRMC has presented market share and market concentration data as evidence that Sentara has a monopoly in open-heart within the service area.

Consistent with these market data, Virginia Health Information (VHI) data demonstrate that Sentara Norfolk General Hospital (SNGH) performed 69.2% of adult cases performed in cardiac operating rooms (ORs) in PD 20 in 2020, the most recent year that data are available from VHI. Combined with volumes performed at Sentara Virginia Beach General Hospital's (SVBGH) exclusive use cardiac room, Sentara hospitals performed 73.8% of adult cardiac OR volumes in PD 20 in 2020 (See Table 6).

The Herfindahl Hirschman Index ("HHI") is a common measure of market concentration used by health care economists to measure market competitiveness. The HHI, which is the sum of square market shares, ranges from one to 10,000. The Federal Trade Commission ("FTC"), the Department of Justice ("DOJ"), and health care economists consider an HHI of 2,500 to be a highly concentrated market, and the higher the score being a more concentrated (indicating monopoly) market. Utilizing the volumes in cardiac ORs reported to VHI as market share, the HHI in PD 20 in 2020 is 5,495 (SNGH and SVBGH included as separate entities). This is more than twice what is considered to be "highly concentrated." In short, SNGH's very high market share is considered monopolistic in PD 20. Letters of support from Anthem and Aetna insurers, and from James V. Koch, Professor of Economics Emeritus at Old Dominion University, predict that additional competition in the open-heart arena in PD20 would be beneficial to improve patient choice, lower costs and improve quality, increasing access to these services in PD 20.

Geographically, CRMC is located less than a half-mile from I-664 and less than two miles from I-64. CRMC asserts that it is located within one hour's driving time of all residents of Southside Hampton Roads. Additionally, public transport to CRMC is readily available by Hampton Roads Transit's Robert Hall Boulevard stop.

According to the State Medical Facilities Plan ("SMFP"), reasonable access to open-heart surgical services is determined on a planning district basis. As shown in Figure 1, current open-heart surgical services are within 60 minutes driving time under normal conditions of 95% of the population living in PD 20. Traffic congestion, however, is a regular complaint of those attempting to navigate the bridges and bottlenecks of PD 20 and represents transportation and geographic barriers. Drive times in PD 20 vary based on time of day and predicted and unpredicted traffic blockages. The proposed project would be located in a facility that is more accessible to the southern part of PD 20 without the common traffic bottlenecks associated with travel to any of the existing open-heart services. It would have a positive impact on geographical access to this service in PD 20.

Population plays a major role in determining the need for certain medical services in a planning district. As depicted in Table 3, at an average annual growth rate of 0.39% (2020 to

2030) PD 20's population growth rate is projected to be slower than Virginia's overall projected growth rate (0.76%) in the current decade. In the 65+ age group, however, PD 20's average annual growth rate (2.87%) is projected to be higher than Virginia's (2.45%) 2020 to 2030. Overall, PD 20 is projected to add an estimated 47,742 people in the 10-year period ending in 2030—an increase of approximately 4,774 people annually. Most of the projected population increase in PD 20 is attributed to Chesapeake City (21,262), Suffolk (14,691) and Virginia Beach City (9.488).

Chesapeake City, where the proposed project would be located, has overtaken Norfolk as the second most populated locality in the planning district. It is projected that by 2030, 21.5% of the population of PD 20 will live in Chesapeake City (Table 8). The growth rate in Chesapeake among the 65+ age cohort is projected to be an average of 3.6% annually (2020 to 2030). That is 26% faster than the overall PD 20 projected average annual growth rate of that age group and 47% faster than Virginia's overall growth of the 65+ cohort for the current decade. Within the current decade, Chesapeake is experiencing higher than average growth and aging versus PD 20 overall, pointing to a faster-growing need for cardiac services in that geographic area.

Table 3. Population Projections for PD 20, 2010-2030

Locality	2010	2020	% Change 2010-2020	Avg Ann % Change 2010-2020	2030	% Change 2020-2030	Avg Ann % Change 2020-2030
Isle of Wight	35,270	38,060	7.91%	0.75%	41,823	9.89%	0.95%
Southampton	18,570	17,739	-4.47%	-0.45%	17,711	-0.16%	-0.02%
Chesapeake	222,209	249,244	12.17%	1.13%	270,506	8.53%	0.82%
Franklin	8,582	8,268	-3.66%	-0.36%	8,140	-1.55%	-0.16%
Norfolk	242,803	246,881	1.68%	0.16%	249,889	1.22%	0.12%
Portsmouth	95,535	95,027	-0.53%	-0.05%	90,715	-4.54%	-0.46%
Suffolk	84,585	94,733	12.00%	1.11%	109,424	15.51%	1.45%
Virginia Beach	437,994	457,699	4.50%	0.43%	467,187	2.07%	0.21%
Total PD 20	**1,145,548**	**1,207,652**	**5.42%**	**0.52%**	**1,255,394**	**3.95%**	**0.39%**
PD 20 65+	**124,196**	**167,891**	**35.18%**	**2.98%**	**222,845**	**32.73%**	**2.87%**
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)

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

(i) The level of community support for the project demonstrated by citizens, businesses, and governmental leaders representing the area to be served.

DCOPN received numerous letters of support from a diverse group of advocates, including a resolution of support from the Chesapeake City Council (nine signatures); State Senators and Delegates; the Hampton Roads Chamber of Commerce; Riverside Health System, insurance

providers; physicians, including a past President for the Society of Thoracic Surgeons; a former Old Dominion University President and Professor of Economics Emeritus, Department of Veterans Affairs Medical Center; Chesapeake Health Department Director; Currituck (North Carolina) County Board of Commissioners; and residents.

Collectively, these letters articulated the need for the proposed project. For example, several letters emphasized the need for an open-heart surgery program closer to the community than SNGH; some addressed lengthy and increasing wait times endured by open-heart patients at SNGH; some discussed the cost/price benefit to patients of adding a competitor; several letters stated that there is a higher incidence of heart disease in CRMC's service area compared to the Virginia average. One letter included an economic analysis describing the positive economic impact of CRMC and the detrimental effects of what it describes to be SNGH's open-heart monopoly. Another provided supporting arguments for the premise that quality among open-heart programs does not correlate closely with volumes. DCOPN received no letters of opposition for the proposed project.

Public Comment

On September 10, 2022, a notice was published soliciting public comment through October 25. DCOPN received a letter of clarification from Sentara Healthcare to ensure that references from CRMC's application regarding quality of and access to SNGH's open heart program were understood with more clarity. Sentara discussed the prominence and benefits of regionalization of open heart services Virginia, noted the exceptions and proposed that high market concentration is the natural consequence and intent of COPN law. The letter presented transfer data differing from some of the applicant's statements about transfers from CRMC, and it questioned the usefulness of emergency department data in assessing the need for an open heart program. Sentara also presented homogenous procedure and risk-adjusted length of stay data, and quality recognitions and information to demonstrate quality and lengths of stay at SNGH consistent with those across the state. Finally, Sentara sought to update and correct information in the CRMC application regarding hybrid ORs, citing COPN Request No. VA-8659 and noting that BSMMC completed construction on a hybrid OR and began performing cases there in June 2022. The letter also states that SVBGH does not have a hybrid OR.

(ii) The availability of reasonable alternatives to the proposed service or facility that would meet the needs of the population in a less costly, more efficient, or more effective manner.

A reasonable alternative does not exist to an open-heart provider that is easier to access for the large, growing and aging segment of PD 20 that resides on the south side of the James and Elizabeth Rivers. The status quo perpetuates a distribution of cardiac operating rooms that doesn't reflect the population and changing demographics of PD 20 and perpetuates a monopolistic market.

Due to transportation barriers, the population south of the cities of Norfolk and Portsmouth routinely face lengthier travel for care at various times during the day, due to traffic volume

and congestion, especially across the several bridges crossing into Norfolk. The status quo also maintains nearly 70% of open-heart cases at a single facility, creating a single provider with market power detrimental to insurance contracts and patient costs. An additional open-heart program in a location more accessible to a large, growing and aging population in the planning district would alleviate these issues.

The proposed service would allow Chesapeake residents to access a full-spectrum of cardiac services without the barriers that currently exist. The estimated costs of the proposed project, at $5,353,768, are lower in comparison to other similar projects in PD 20. For example, COPN VA-03722 issued to Bon Secours Maryview Medical Center (BSMMC) to introduce open-heart surgery services cost approximately $6,263,582.

(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 V designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 20. Therefore, this consideration is not applicable to the review of the proposed project.

(iv) Any costs and benefits of the project.

The total capital and financing cost for the proposed project is $5,353,768 (Table 2). This is substantially less than CRMC's previous application for open-heart surgery (COPN Request Number VA-8300), which projected costs of $7,853,502. The previous application included additional cardiac catheterization equipment to be used to create a hybrid OR, which is not included in the current proposed project. The current project proposed is also less costly than previously approved projects to add open-heart services and build a new operating room. For example, COPN VA-03722 issued to BSMMC to introduce open-heart surgery services cost approximately $6,263,582. The proposed project to add open-heart surgery will have several benefits, according to the applicant. For example, the applicant asserts that the approval of the project would increase access for residents of Chesapeake and North Carolina to time-sensitive lifesaving procedures in an area plagued with traffic bottlenecks and congestion, and decrease healthcare costs through the addition of needed competition.

(v) The financial accessibility of the project to the residents of the area to be served, including indigent residents.

The applicant states that CRMC has always provided services to patients regardless of ability to pay or payment source. As Table 4 demonstrates, CRMC provided 2.16% of its gross patient revenue in the form of charity care in 2020. This percentage ranked CRMC in the bottom half of providers in HPR V in 2020, just slightly below the average of the 2.5% hospital-wide charity care percentage provided by all reporting facilities in HPR V. In a meeting with DCOPN, CRMC representatives claimed continued commitment to the provision of charity care and asserted that the charity care percentage last published was

lower than its actual percentage, and had excluded cases that had been incorrectly categorized. Should the State Health Commissioner approve the proposed project, CRMC is expected to provide a level of charity care for total gross patient revenues that is no less than the equivalent average for charity care contributions in HPR V.

Table 4. HPR V 2020 Charity Care Contributions

Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Riverside Tappahannock Hospital	$165,747,566	$8,843,478	5.34%
Riverside Shore Memorial Hospital	$247,007,286	$10,695,992	4.33%
Riverside Doctors' Hospital Williamsburg	$149,491,510	$6,064,567	4.06%
Riverside Walter Reed Hospital	$252,482,633	$9,401,927	3.72%
Bon Secours DePaul Medical Center	$363,165,760	$12,756,832	3.51%
Sentara Careplex Hospital	$909,090,883	$31,651,344	3.48%
Sentara Obici Hospital	$914,294,131	$26,301,718	2.88%
Sentara Virginia Beach General Hospital	$1,265,310,067	$36,146,887	2.86%
Sentara Norfolk General Hospital	$3,753,299,758	$106,756,170	2.84%
Sentara Leigh Hospital	$1,330,835,003	$34,335,012	2.58%
Riverside Regional Medical Center	$2,191,107,102	$53,859,556	2.46%
Chesapeake Regional Medical Center	$986,713,280	$21,292,946	2.16%
Hampton Roads Specialty Hospital	$46,913,449	$1,010,073	2.15%
Sentara Princess Anne Hospital	$1,032,703,976	$21,443,232	2.08%
Bon Secours Maryview Medical Center	$1,148,940,309	$22,068,850	1.92%
Bon Secours Mary Immaculate Hospital	$620,268,395	$11,887,663	1.92%
Sentara Williamsburg Regional Medical Center	$655,360,428	$11,516,832	1.76%
Bon Secours Rappahannock General Hospital	$70,546,600	$1,148,522	1.63%
Children's Hospital of the King's Daughters	$1,120,616,182	$4,135,241	0.37%
Bon Secours Southampton Memorial Hospital	$211,414,625	$460,731	0.22%
Lake Taylor Transitional Care Hospital	$44,295,918	$0	0.00%
Hospital For Extended Recovery	$30,370,572	$0	0.00%
Total $ & Mean %	**$17,509,975,433**	**$431,777,573**	**2.5%**

Source: VHI 2020

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

On June 23, 2017, CRMC submitted an application for COPN Request Number VA-8300, which proposed to introduce open-heart surgery at CRMC by adding one hybrid cardiac surgery operating room in the surgical services department of the main hospital. On November 20, 2017, DCOPN issued a staff report recommending conditional approval of COPN Request Number VA-8300. On April 12, 2018, an informal fact finding conference was held at the request of a competing applicant to show good cause. On August 24, 2018, the Commissioner adopted the adjudication officer's recommendation to deny COPN Request Number VA-8300. On October 19, 2018, CRMC filed a petition to appeal the Commissioner's decision denying COPN Request Number VA-8300. Although the courts

determined that the interpretation and need calculation that the Commissioner relied on was in error, they concluded it was a "harmless error." On May 19, 2022 the Virginia Supreme Court overturned the Circuit Court ruling and remanded the project back to the Commissioner to review again. COPN Request Number VA-8300 is on hold pending the resolution of the current application, which was filed due to uncertainty about the courts' ultimate decision.

CRMC also submitted COPN Request Number VA-8427 on January 29, 2019, to introduce open heart surgery and utilize one OR and cardiac catheterization equipment as a hybrid OR for open and closed heart procedures. This application was later withdrawn.

The following evaluation based upon the State Medical Facilities Plan is consistent with the most recent Virginia Supreme Court ruling, examining volumes by service rather than operating room or cardiac catheterization lab.

3. The extent to which the application is consistent with the State Medical Facilities 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 State Medical Facilities Plan (SMFP).The SMFP contains criteria/standards for the establishment of open-heart surgery services. They are as follows:

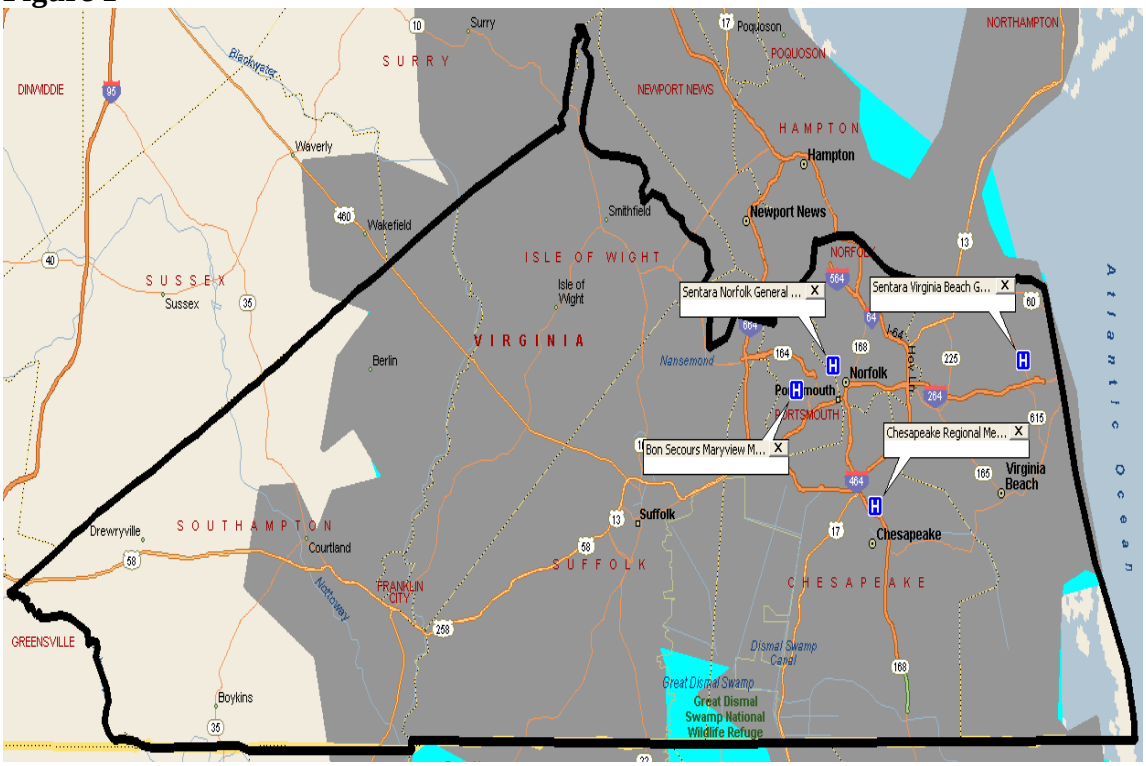
Part IV
Cardiac Services
Article 2
Criteria and Standards for Open Heart Surgery

12VAC5-230-440. Travel time.
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 20. The grey shaded area includes all locations that are within 60 minutes driving time one way under normal conditions of open-heart surgical services in PD 20. The light 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. Since only part of Southampton County is not currently accessible within 60 minutes of existing services (Table 8 indicates this county in total is 1.4% of the PD 20 population), Figure 1 clearly illustrates that open-heart surgical services are already within a one-hour drive under normal conditions of 95% of the residents of the planning district. Traffic congestion, however, is a regular complaint of those attempting to navigate the bridges and bottlenecks of PD 20. The applicant asserts that, while

at least 95% of the population in PD 20 is within 60 minutes driving time of existing open-heart surgical services, approval of the project will increase the accessibility for patients travelling to CRMC from North Carolina. While DCOPN acknowledges CRMC's commitment to providing care to the underserved residents of those areas of North Carolina specified in their application, this falls outside of the scope of Virginia COPN law. CRMC additionally states that traffic congestion is a problem for residents of PD 20 attempting to navigate the drawbridges and tunnels that separate Chesapeake and Norfolk. These barriers appear to be less acute between Chesapeake and Portsmouth where BSMMC's open-heart program is located; however, DCOPN recognizes that legitimate barriers exist for the residents of PD 20 to accessing current PD 20 open-heart programs from the south. The proposed project would be located in a facility that does not already have open-heart surgery capability, in a city projected to experience high grown, especially in the 65+ age group. The proposed project would have some positive impact on geographical access to this service in PD 20.

Figure 1



A. 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;

CRMC is an inpatient hospital. Table 5 summarizes CRMC's cardiac catheterization DEP volumes for the latest three years available from VHI. Though CRMC dipped below the 1,200 DEP threshold in 2020 by six cases (99.5% of the threshold), decreased volumes were common during 2020 due to COVID-19 impacts. The applicant has provided data for fiscal years 2021 and 2022 that demonstrates its cardiac catheterization DEPs have not only rebounded but grown to 1,916 in 2022, 160% of the threshold set forth in the SMFP. Furthermore, CRMC's cardiac catheterization lab has been in operation for greater than 30 months.

Table 5. CRMC Cardiac Catheterization DEPs

Cardiac Cath Type	2018	2019	2020
Diagnostic	575	557	484
Therapeutic	127	7	4
Diagnostic & Therapeutic (Same Session)	359	293	234
Total DEPs	1,906	1,450	1,194

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

According to 2020 VHI data, the three facilities in PD 20 with adult open-heart programs performed an average of 817 cases per service (Table 6). SVBGH performed far fewer than 400 cases; however, SNGH had nearly five times this threshold of cases in its cardiac ORs. Sentara may have the ability to consolidate or spread these volumes between its two sites and, as a system, averages 904 cases per program.

Table 6. Average Cases per Service in Cardiac ORs, PD 20

Facility	Cases performed in Cardiac ORs	% of Total
Bon Secours Maryview Medical Center	643	26.2%
Sentara Norfolk General Hospital	1,697	69.2%
Sentara Virginia Beach General Hospital	111	4.5%
Total Cases	**2,451**	100.0%
Average per Open-heart Service	**817**	

Source: VHI 2020

The applicant has pointed out that 12VAC5-230-450 A.2. is based upon procedures, but the VHI data utilized for calculations are based on cases. Because there are sometimes multiple procedures per case, the actual number of procedures performed in cardiac ORs will be higher

than cases. In addition, the applicant asserts that VHI-reported volumes may include cases that aren't in the category of "open heart and closed heart." The VHI claims-based volumes that the applicant proposes to use (Table 7) are actually lower than those reported to VHI in the Annual Licensure Survey, especially for BSMMC, but still yield a case per service number above the 400-procedure threshold:

Table 7. Open and Closed Heart Cases by Existing PD 20 Service	**FY2020**	**FY2021**	**FY2022**
Sentara Norfolk General Hospital	1541	1499	1660
Sentara Virginia Beach General Hospital	76	159	137
Bon Secours Maryview Medical Center	51	90	47
Total	**1668**	**1748**	**1844**
Cases Per Service	**556**	**583**	**615**
Chesapeake City Cases			
SNGH	214	199	216
SVBGH	2	21	9
BSMMC	6	15	11
All Others	11	13	29
Total	**233**	**248**	**265**

*Source: Virginia Inpatient Claims Database (accessed via VHHA). FY based on July 1 - June 30.

Data through March 2022 for FY2022 beginning July 1, 2021 with last quarter estimated.

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 total number of open and closed heart cases performed in PD 20 facilities was 1,688 in FY 20 and increased to 1,844 by FY22 (Table 7). It is logical that Chesapeake City cases will make up a majority of open and closed heart cases performed at CRMC, should the proposed project be approved. Though DCOPN cannot justify need for an open-heart program with populations outside of the planning district, it is reasonable to assume that the North Carolina populations CRMC is attempting to serve would contribute additional volumes to the proposed project. The applicant projects that it will perform 178 open-heart cases in its first full year of operation and 268 open-heart and TAVR cases its second year. These projections appear reasonable.

The applicant asserts that few patients from Chesapeake currently utilize BSMMC or SVBGH, so the proposed project would not significantly reduce utilization of either of these programs. Table 7 supports this assertion. Over the past three years, 84% of Chesapeake City residents have received their open and closed heart services from SNGH and only 4% have gone to each of the other PD 20 programs. The number of cases out-migrating from PD 20 has more than doubled in the past year, according to VHI claims data presented.

Table 8. Percentage of PD 20 Population

County/City	2010	2020	2030	Estimated Adult Cardiac OR cases by City/County
Isle of Wight	3.1%	3.2%	3.3%	77
Southampton	1.6%	1.5%	1.4%	36
Chesapeake	19.4%	20.6%	21.5%	506
Franklin	0.7%	0.7%	0.6%	17
Norfolk	21.2%	20.4%	19.9%	501
Portsmouth	8.3%	7.9%	7.2%	193
Suffolk	7.4%	7.8%	8.7%	192
Virginia Beach	38.2%	37.9%	37.2%	929
Total PD 20	**100.0%**	**100.0%**	**100.0%**	**2,451**

Source: Calculated from Weldon-Cooper Center Projections

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 not more than 60 minutes driving time from other sites where open-heart surgery services are 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 drive time one way under normal conditions of an existing open heart surgery service in the health planning district.**

Not applicable. The proposed project is not an existing 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 add 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.

Should the proposed project receive approval, CRMC will appoint Thomas L. Carter, M.D., FACS as medical director. Dr. Carter is currently on the active staff in CRMC and is board certified by the American Board of Surgery and the American Board of Thoracic Surgery. He has provided a letter of commitment to serve as program director, should the proposed project be approved.

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 seeking to establish pediatric cardiac 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 seeking to establish pediatric cardiac surgery services.

4. The extent to which the proposed service or facility fosters institutional competition that benefits the area to be served while improving access to essential health care services for all persons in the area to be served.

Given that CRMC does not currently perform open-heart surgery within PD 20, approval of the proposed project would foster institutional competition through the introduction of a fourth provider in a market with a monopolistic provider, SNGH. Sentara has market power in the area of open-heart surgery in PD 20, controlling 75% of adult cardiac operating rooms and nearly 74% of volumes. This level of market concentration in a specialized service creates negotiating power with payers and has the potential to inflate health care costs for patients.

Added competition from the proposed project is likely to benefit patients. Because the majority of open-heart patients from Chesapeake currently utilize the open-heart program at SNGH, the proposed program at CRMC would foster competition with SNGH's dominant program without significant impact to BSMMC or SVBGH. There is an argument that institutional competition is not beneficial if it deprives providers of adequate volumes to develop strong patterns, protocols and quality measures. The applicant has presented projections of volumes that meet SMFP guidelines, and arguments that open and closed heart surgery technology and protocols have matured such that low-volume programs implementing best practices have strong quality outcomes.

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

PD 20 has three open-heart programs within 60 minutes of the proposed project. SNGH and SVBGH are part of the same health care system, Sentara Health. BSMMC operates a smaller program. All other things equal, an additional open-heart service would diminish volumes at existing programs in the planning district; however, projected changes in demographics in PD 20 would likely mitigate this.

In past decisions the Commissioner has relied on the assertion that a direct correlation exists between higher volumes of open-heart surgery cases at a facility and lessened instances of mortality and morbidity. While there have been some challenges to this correlation in recent COPN applications, the Commissioner, as recently as 2018, has given a great deal of weight to this connection between volume and lessened instances of mortality and morbidity[1]. The applicant has challenged the assertion that volumes substantially impact quality, and submitted a letter of support from an expert in quality measurement of open heart programs, Dr. Jeffrey B. Rich, MD.

Dr. Rich has served as the President of the Society of Thoracic Surgeons ("STS"), nationally, including participation in the STS Quality Committee, as director of the Center for Medicare

[1] Adjudication Officer's Report, COPN Request No. VA-8300 (Adopted by the Commissioner on August 24, 2018).

Management at CMS, as Chair of Strategic Operations at the Heart and Vascular Institute at the Cleveland Clinic, and was co-founder of the Virginia Cardiac Services Quality Initiative (VCSQI) (among other positions). These roles included the development and analysis of quality metrics and evaluation of programs, including open-heart programs.

Dr. Rich points specifically to current Virginia programs and data:

> *"…the current make-up of the VCSQI includes 17 hospitals that are authorized to perform cardiac surgery. Five of these programs perform less than 100 cases per year, five perform between 100 and 200 cases per year, and the remaining seven hospitals perform more than 200 cases per year. Within each of these groups are outliers. A finding that volume equals quality is simply not possible when we examine these hospitals."*

More definitively, Dr. Rich states:

> *"The articles that suggest a link between quality and volume are based on studies and analyses that occurred twenty to thirty years ago. These studies are outdated, and more recent analyses reveal that there is no longer such a correlation regarding CABG procedures."*

More recent studies than the 2002 study that initially associated higher case volume and lower perioperative mortality[2] are consistent with Dr. Rich's experiences. A 2021 review of quality initiatives[3], for example, cited several studies that found that the association of CABG outcomes with volume is weak[4] and, consistent with Dr. Rich's assertions, "adherence to evidence-based metrics is more important than volume alone."[5]

In a meeting with the DCOPN, both Dr. Rich and Dr. Carter discussed the evolution of open and closed heart programs. Dr. Carter, who has committed to serve as the program director should the proposed project be approved, stated that in the early years of cardiac surgery, open heart programs with high volumes did have better quality and outcomes than lower-volume programs, but that is no longer the case. In his letter, Dr. Carter writes about factors that now contribute to successful open heart programs:

> *These factors, and others like them, are driven by protocols; protocols which are evidence based, published in the literature, taught in conferences and learned in training. These protocols take the knowledge and wisdom gained from high volumes of patient observations and outcomes and distill them into specific orders and actions thereby minimizing errors, avoiding bad outcomes and increasing efficiencies. They are straight forward, reproducible and proven to work. Since these protocols have been proven to*

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[2] Birkmeyer JD, Siewers AE, Finlayson EV, Stukel TA, Lucas FL, Batista I et. al. Hospital volume and surgical mortality in the United States. *N Engl J Med*. 2002; 346 (15):1128-37.

[3] Vikas S, Glotzbach JP, Ryan J and Seizman C. Evaluating Quality in Adult Cardiac Surgery. Tex Heart Inst J, 2021:48(1):e197136.

[4] Rathmore SS, Epstein AJ, Volpp KGM, Krumholz HM, Hospital coronary artery bypass graft surgery volume and patient mortality, 1998-2000.*Ann Surg*.2004;239(1):110-7.

[5] Schwartz DM, Fong ZV, Warshaw AL, Zinner MJ, Chang DC. The hidden consequences of the volume pledge: "no patient left behind"? *Ann Surg*. 2017;265(2):273-4.

work in a high volume of patients across multiple institutions, their implementation and effectiveness are not contingent on volume at a particular institution but on the willingness of the cardiac surgery administrative, medical and nursing leadership at that institution to write them, implement them, teach them and ensure they are followed.

CRMC is not part of a larger health care system, but espouses a Heart Team approach to cardiac care. Dr. Carter has asserted in his letter that the proposed project would have a positive impact on continuity of care for patients that choose CRMC for their cardiac needs.

With proven, evidence-based quality protocols, smaller open-heart programs can certainly demonstrate high quality and outcomes as can higher-volume programs. Nevertheless, the applicant asserts that the proposed project would not decrease volumes significantly at the smaller PD 20 programs because few patients from Chesapeake currently utilize BSMMC or SVBGH. Instead, the majority of volume shifts would occur from SNGH and retention of the growing number of patients out-migrating to programs outside of PD 20. Table 7 supports this assertion, as 84% of Chesapeake City residents have received their open and closed heart services from SNGH in the past three years (629 of 746), and only 4% have gone to SVBGH (32 of 746) and 4% to BSMMC (32 of 746). The number of patients going to programs outside of PD 20 has grown from 11 in 2020 to 29 in 2022.

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

DCOPN believes that the projected costs for the project are reasonable. The total capital and financing cost for the project is $5,353,768 (Table 2). This is substantially less than CRMC's previous application for open-heart surgery, which projected costs of $7,853,502 and included costs of a hybrid OR. The costs for the project are reasonable and consistent with previously approved projects to add open-heart services that proposed to build a new operating room. For example, COPN VA-03722 issued to BSMMC to introduce open-heart surgery services, which cost approximately $6,263,582. The proposed project would be funded through CRMC's accumulated reserves. Based on the financial statements provided by the applicant, DCOPN concludes that the project is financially feasible. The applicant asserts that the proposed project will inject beneficial competition and lower the costs of open-heart surgery for residents in CRMC's primary service area.

CRMC states in its application that it anticipates needing 14.0 FTEs for the proposed project and that adding these positions will "likely will have little, if any, impact on the staffing of other facilities in the service area." The necessary positions, however, are highly specialized and competition for these positions may have some detrimental effect on staffing at existing open-heart surgery programs in PD 20. CRMC states that it will "make a good faith effort to recruit and hire personnel for the proposed project from outside of PD 20;" however, hiring decisions will be based on best-qualified candidates.

7. The extent to which the project provides improvements or innovations in the financing and delivery of health 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 services on an outpatient basis; (iii) Any cooperative efforts to meet regional health care needs; (iv) At the discretion of the Commissioner, any other factors as may be appropriate.

Should the proposed project receive approval, CRMC will construct a state-of-the-art operating room dedicated to cardiac surgery. The operating room will be built with the latest medical advancements in mind so that it can accommodate hybrid heart procedures, such as TARV, in the future. No 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.

Not applicable. The applicant is not a teaching hospital or affiliated with a public institution of higher education or medical school in the area to be served. Approval of the proposed project would not contribute to the unique research, training or clinical mission of a teaching hospital or medical school.

DCOPN Findings and Conclusions

DCOPN finds that the proposed project to establish open-heart surgery at CRMC is generally consistent with the applicable criteria and standards of the SMFP and the eight Required Considerations of the Code of Virginia. The recent Virginia Supreme Court decision has upheld the DCOPN's original interpretation of 12VAC5-230-450(A)(2) that led to a recommendation of conditional approval of COPN Request Number VA-8300.

DCOPN concludes that the proposed project would inject beneficial competition into a concentrated open-heart market with one dominant provider, which will improve patient choice and reduce health care costs in PD 20. The project appears unlikely to reduce utilization of PD 20's existing, lower-volume open-heart programs, and the applicant has presented evidence that

open-heart programs with lower volumes than those in PD 20 are no more likely to have quality concerns than larger programs.

Additionally, DCOPN finds that the status quo perpetuates a distribution of cardiac operating rooms that doesn't reflect the population and changing demographics of PD 20. Chesapeake has the second-highest population of municipalities in the planning district, and is experiencing higher than average growth and aging, pointing to a faster-growing need for cardiac services in that geographic area.

While open-heart surgery services are available within a sixty-minute drive, one-way, from over 95% of the population of PD 20, traffic congestion represents legitimate transportation and geographic barriers such that the proposed project would have a positive impact on geographical access in the southern part of the planning district. While the applicant has made the argument that some residents of North Carolina who travel to CRMC for medical care are not within a sixty-minute drive, one-way of an open-heart surgery program, the need of residents of North Carolina is outside the scope of Virginia COPN law. It is likely, however, that North Carolina residents will add volumes to the proposed service.

Finally, DCOPN finds that the proposed project is feasible, has reasonable estimated costs and will be funded by accumulated reserves. It has an adequate base of cardiac catheterizations and other cardiac-related services to support an open-heart program.

DCOPN Staff Recommendations

The Division of Certificate of Public Need recommends the **conditional approval** of Chesapeake Regional Medical Center's COPN Request Number VA-8662 to introduce open-heart surgery at CRMC. DCOPN's recommendation is based on the following findings:

1. The proposed project is generally 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 proposed project will improve access for a large, growing and aging segment of PD 20.

3. It will inject beneficial competition in a highly-concentrated open-heart surgery market, improving patient choice and reducing health care costs without significantly reducing the volumes of smaller programs in the planning district.

4. Capital costs are reasonable and the project is financially feasible.

5. There appears to be no reasonable alternative to the proposed project.

DCOPN's recommendation is contingent upon Chesapeake Regional Medical Center's agreement to the following charity care condition:

Chesapeake Regional Medical Center will provide open and closed heart surgical services to all persons in need of this service, regardless of their ability to pay, and will facilitate the development and operation of primary medical care services to medically underserved persons in PD 20 in an aggregate amount equal to at least 2.5% of Chesapeake Regional Medical Center's gross patient revenue derived from open and closed 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. Chesapeake Regional Medical Center 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.

Chesapeake Regional Medical Center will provide open and closed 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, Chesapeake Regional Medical Center will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.