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

Staff Analysis

December 20, 2019

COPN Request No. VA-8427
Chesapeake Regional Medical Center
Chesapeake, Virginia
Introduce 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 a 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. CRMC's primary service area includes the city of Chesapeake, the southern part of the city of Virginia Beach, and the city of Norfolk. CRMC is located in Planning District (PD) 20 within Health Planning Region (HPR) V.

Background

CRMC has been in operation for over forty-three years and provides a variety of services, including obstetrics, oncology and radiation therapy, cardiac catheterization, diagnostic imaging, and 13 general purpose operating rooms. As demonstrated by Table 1, the adult cardiac surgical inventory of PD 20 consists of seven general use cardiac operating rooms and one operating room used exclusively for adult cardiac surgery across three sites.

Table 1. PD 20 COPN Authorized Adult Cardiac Surgery Operating Rooms: 2017

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")

Proposed Project

CRMC proposes to introduce open-heart surgery by constructing an operating room dedicated to cardiac surgery adjacent to the surgery services department on the hospital's second floor. CRMC asserts that the new operating room will be state of the art, with the latest medical advancements in mind so that it can accommodate hybrid heart procedures, such as transcatheter aortic valve

replacement (TAVR), in the future. CRMC asserts that, should the proposed project be approved, they will delicense one general-purpose operating room when the cardiac surgery operating room is completed. While this would make the proposed project inventory neutral concerning operating rooms, it would increase the total number of open-heart surgical programs in PD 20 by one. The total capital and financing costs for the project are $6,162,670 (Table 2) and would be paid for by the use of CRMC accumulated reserves.

Table 2. Capital and Financing Costs

Direct Construction Costs	$3,088,321
Equipment Not Included in Construction Contract	$2,567,349
Site Preparation Cost	$160,000
Architectural and Engineering Fees	$272,000
Other Consultant Fees	$75,000
TOTAL Capital and Financing Costs	**$6,162,670**

Source: COPN Request No. VA-8427

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 constructing an operating room dedicated to cardiac surgery adjacent to the surgery services department on the hospital's second floor. Currently, open-heart surgery exists at three locations in PD 20. In their application, CRMC asserts that Sentara dominates the market in PD 20 for open-heart surgery. This assertion is supported by VHI's 2017 open heart surgery volume (Table 6 below), which shows that Sentara hospitals, primarily Sentara Norfolk General Hospital ("SNGH"), provided over 70% of the open heart surgeries in PD 20 for that year. As the proposed project would be located in a facility owned by a health system that does not currently offer open-heart surgery, approval of the proposed project would provide beneficial competition 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. Access is determined by the availability of open-heart surgical services within 60 minutes driving time under normal conditions of 95% of the population living in PD 20. As shown in Figure 1, found in 12VAC5-230-440 (approximately page 8) below, open-heart surgery services are readily accessible to the residents of PD 20. Traffic congestion, however, is a regular complaint of those attempting to navigate the bridges and bottlenecks of PD 20. While DCOPN adopts the previous decision made by the Commissioner that approval of the project would not significantly improve geographic access to open-heart surgical services for the residents of PD 20[1], it does recognize that, 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 20.

Population plays a major role in determining the need for certain medical services in a planning district. Table 3 shows projected population growth in PD 20 through 2020.

As depicted in Table 3, at an average annual growth rate of 0.52%, PD 20's population growth rate is slightly greater than two-thirds of the state's average annual growth rate of 0.77%. Overall, the planning district is projected to add an estimated 62,104 people in the 10-year period ending in 2020—an increase of approximately 6,210 people annually. Most of the population increase in PD 20 is attributed to Virginia Beach City, Norfolk City, and Chesapeake City.

Chesapeake City, where the proposed project would be located, is the third most populated locality in the planning district, with a projected population of 249,244 in 2020, up from 222,209 in 2010. The average annual growth between 2010 and 2020 is a 1.13%, over double the average of the planning district, and represents the fastest growing area in the planning district. It is projected that by 2020, over 20% of the population of PD 20 will live in Chesapeake City.

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

Table 3. Population Projections for PD 20, 2010-2020

Locality	2010	2020	% change	Avg Ann % Chg
Isle of Wight	35,270	38,060	7.91%	0.75%
Southampton	18,570	17,739	-4.48%	-0.45%
Chesapeake City	222,209	249,244	12.17%	1.13%
Franklin City	8,582	8,268	-3.66%	-0.36%
Norfolk City	242,803	246,881	1.68%	0.16%
Portsmouth City	95,535	95,027	-0.53%	-0.05%
Suffolk City	84,585	94,733	12.00%	1.11%
Virginia Beach City	437,994	457,699	4.50%	0.43%
Total PD 20	**1,145,548**	**1,207,652**	**5.42%**	**0.52%**
Virginia	8,001,024	8,655,021	8.17%	0.77%

Source: U.S. Census, Weldon Cooper Center Projections (2017) 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 individuals from the following:

- U.S. Congressman Robert C. "Bobby" Scott
- Five members of the Virginia House of Delegates
- Two members of the Virginia Senate
- Six Chesapeake City Council Members
- The Vice Mayor of the City of Chesapeake
- The Chesapeake Health District Director
- The Chesapeake City Manager
- The City of Chesapeake Chief of Police
- The City of Chesapeake Fire Chief
- The City of Chesapeake Sheriff
- The President of the Currituck Chamber of Commerce
- The Currituck County Board of Commissioners
- Two third party payers
- Seven physicians
- Over 1,400 members of the public

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 Sentara Norfolk General Hospital. Moreover, several letters stated that there is a higher incidence of heart disease in CRMC's service area compared to the Virginia average.

DCOPN received one letter of opposition from a member of the public. This letter did not directly address the proposed project, but instead stated that the individual did not believe that the government should require a certificate of need for any individual or business to open a facility.

DCOPN received one letter of opposition for the proposed project from Bon Secours Hampton Roads. TAVR In this letter, Bon Secours articulated a lack of need for a fourth adult cardiac program in PD 20 and stated that available capacity exists at Sentara Virginia Beach Hospital and Bon Secours Maryview Medical Center. Bon Secours additionally stated that approval of the project would project would significantly reduce the open-heart surgery volume of existing providers. In support of this, Bon Secours cited the many public comments and letters that clearly indicated a redirection of services from existing providers would result from the approval of the project. Lastly, Bon Secours stated that approval of the project would have a detrimental effect on staffing at the existing open-heart surgery programs. Bon Secours states that the required positions are highly specialized, very competitive and expensive to recruit, and challenging to retain. In support of this assertion, Bon Secours cites the health system's experience with this issue throughout the Commonwealth and specifically at Bon Secours Maryview Medical Center, where they have vacancies in several of these critical cardiac positions.

Public Hearing

DCOPN conducted the required public hearing on December 9, 2019. A total of 48 individuals were in attendance. Thirty-five individuals in attendance indicated that they were in support of the proposed project and three individuals indicated that they opposed the proposed project. The project was presented by four representatives from CRMC. Twenty-six members of the public spoke in support of the proposed project. Collectively, they discussed their personal positive experiences with CRMC and asserted that there was a need for an open-heart surgery program within Chesapeake. Two members of the public spoke in opposition of the proposed project. Collectively, they asserted that the open-heart surgery section of the SMFP clearly showed that there was not a need for another open-heart surgery program in the planning district and that approval of the project would have a detrimental effect on existing open-heart surgery providers.

(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.

The status quo is a reasonable alternative to the proposed project. As discussed in greater detail below, current utilization in PD 20 does not necessitate the addition of another open-heart surgical program. The addition of another program would likely either result in a low volume service at CRMC that would fail to meet the required standards of the SMFP, or a decrease in the volume of cases at existing open-heart programs in PD 20. DCOPN finds that neither is acceptable, as there is strong evidence of a correlation between open-heart surgical volume and rates of mortality and morbidity[2].

[2] 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. and 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.

(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 project is $6,162,670 (Table 2). This is substantially less than CRMC's previous application for open-heart surgery, which projected costs of $7,853,502. 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 Maryview Medical Center to introduce open-heart surgery services, which 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.

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

As Table 4 below demonstrates, CRMC provided 1.32% of its gross patient revenue in the form of charity care in 2017. This percentage is the fifth lowest in HPR V in 2017, and well below the average of the 4.6% hospital-wide charity care percentage provided by all reporting facilities. Accordingly, 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 2017 Charity Care Contributions

Health Planning Region V 2016 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	**Gross Patient Revenues**	**Adjusted Charity Care Contribution**	**Percent of Gross Patient Revenue**
Riverside Tappahannock Hospital	$170,161,862	$14,424,688	8.48%
Riverside Shore Memorial Hospital	$213,836,867	$15,554,845	7.27%
Riverside Walter Reed Hospital	$233,803,068	$16,337,534	6.99%
Riverside Doctors' Hospital Williamsburg	$113,798,697	$7,874,709	6.92%
Sentara Careplex Hospital	$881,940,507	$59,719,527	6.77%
Bon Secours DePaul Medical Center	$727,116,835	$47,573,800	6.54%
Bon Secours Maryview Medical Center	$1,270,130,980	$82,626,281	6.51%
Riverside Regional Medical Center	$1,724,979,089	$97,953,743	5.68%
Sentara Obici Hospital	$825,358,832	$46,178,990	5.60%
Sentara Virginia Beach General Hospital	$1,265,410,000	$58,414,291	4.62%
Sentara Leigh Hospital	$1,165,281,214	$53,576,119	4.60%
Sentara Norfolk General Hospital	$3,069,620,000	$136,010,038	4.43%
Sentara Princess Anne Hospital	$932,726,000	$38,685,082	4.15%
Sentara Williamsburg Regional Medical Center	$597,649,239	$23,639,676	3.96%
Bon Secours Rappahannock General Hospital	$78,684,125	$2,548,322	3.24%
Bon Secours Mary Immaculate Hospital	$651,234,139	$19,170,988	2.94%
Hampton Roads Specialty Hospital	$11,321,075	$190,354	1.68%
Southampton Memorial Hospital	$210,036,877	$3,066,585	1.46%
Chesapeake Regional Medical Center	$852,854,961	$11,283,609	1.32%
Children's Hospital of the King's Daughters	$953,468,491	$4,532,724	0.48%
Hospital For Extended Recovery	$27,317,785	$0	0.00%
Lake Taylor Transitional Care Hospital	$45,075,260	$0	0.00%
Total $ & Mean %	**$16,021,805,903**	**$739,361,905**	**4.6%**

Source: 2017 VHI Data

(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 No. 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 No. VA-8300. On April 12, 2018, an informal fact finding conference was held at the request of a competing applicant. On August 24, 2018, the Commissioner adopted the adjudication officer's decision to deny COPN Request No. VA-8300. On October 19, 2018, CRMC filed a petition to appeal the Commissioner's decision denying COPN Request No. VA-8300. The case was heard in City Circuit Court on November 7, 2019. The court issued a ruling dated November 27, 2019, which, at the time of this staff report, has not yet incorporated into an Order.

3. The extent to which the application is consistent with the State Medical Facilities Plan.

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

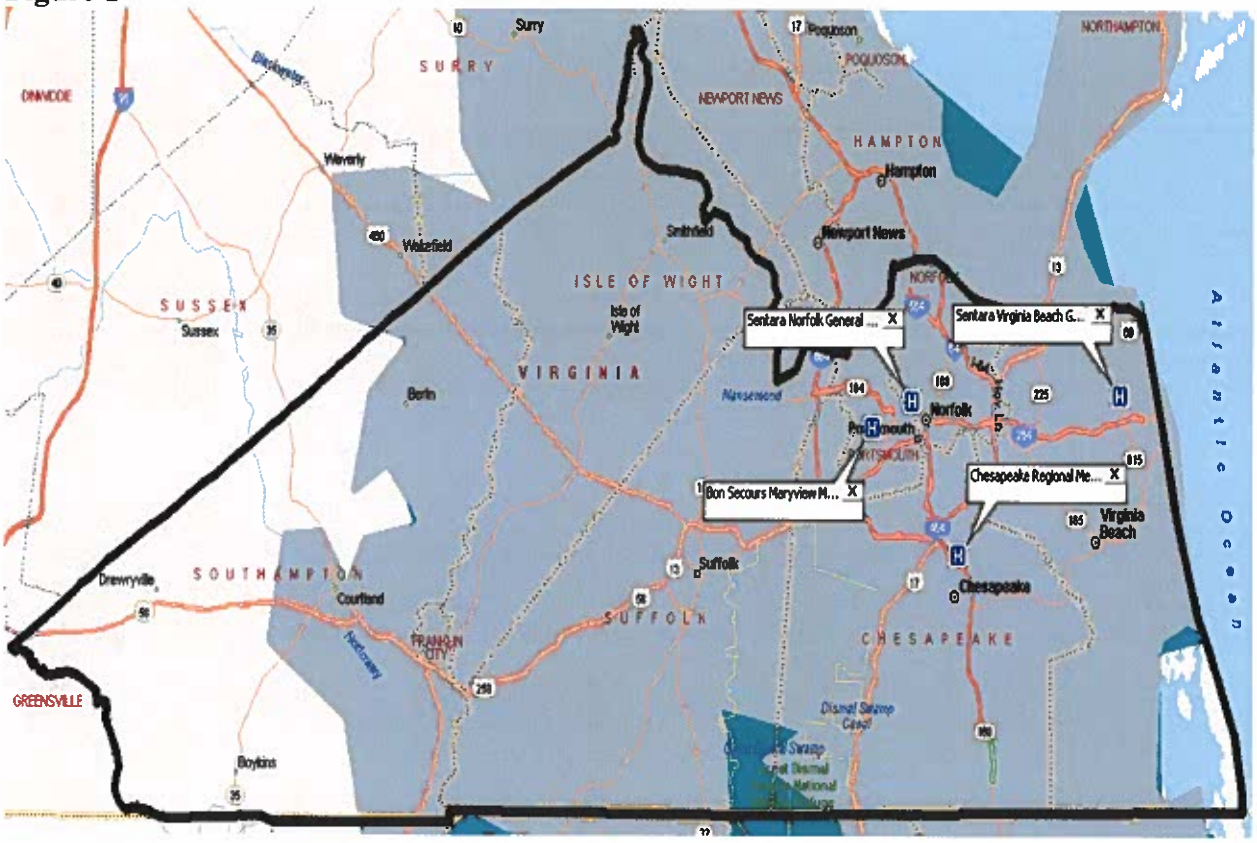
12VAC5-230-440. Travel time.

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 commission.

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. Figure 1 clearly illustrates that open-heart surgical services are already well 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 are 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. While DCOPN adopts the previous decision made by the Commissioner that approval of the project would not significantly improve geographic access to open-heart surgical services for the residents of PD 20[3], it does recognize that, 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 20.

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

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 services 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. A recent decision by the Fourth Circuit Court of Virginia upheld the Commissioner's interpretation that this section should be read to be evaluated per cardiac catheterization lab[4]. As such, DCOPN adopts this interpretation for its review of this project.

[4] Chesapeake Hospital Authority d/b/a Chesapeake General Hospital v. State Health Commissioner et. al. (Civil Docket No. CL18-6997)

Table 5 below shows the cardiac catheterization diagnostic equivalent procedures for CRMC in 2013 through 2017. CRMC has yet to exceed the required threshold of 1,200 DEPs in the past five years. As such, DCOPN concludes that the applicant has not satisfied this standard.

Table 5. Adult Cardiac Catheterization Utilization (in DEPs) at CRMC, 2013-2017

	Cardiac Cath Labs	Diagnostic	Therapeutic	Same Session	Total DEPs[5]	DEPs per Lab	Utilization Rate
2013	2	580	64	182	1254	627	52.25%
2014	2	652	81	222	1480	740	61.67%
2015	2	613	17	246	1385	692.5	57.71%
2016	2	521	29	244	1311	655.5	54.63%
2017	2	506	84	329	1661	830.5	69.21%

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[6]. CRMC, in their application, presents the cases per facility or per health system interpretation. This interpretation ignores the Commissioner's decision in COPN Request No. VA-8300, regarding CRMC's previous application for open-heart surgery. In this decision, the Commissioner clearly determined that "services" should be interpreted to mean per operating room[7]. DCOPN, in past reviews, has viewed the Commissioner's decision as instructive[8]. A recent decision by the Fourth Circuit Court of Virginia, however, determined that this section should be read to be evaluated by facility[9]. DCOPN adopts this interpretation for its review of this project.

Table 6 below shows the adult open-heart surgery volume for PD 20 in 2017, the most recent year for which DCOPN has received data from VHI. In 2017, an average of 885.3 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] 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).
[6] COPN Request Nos. VA-8300, VA-8306, & 8436.
[7] Adjudication Officer's Report, COPN Request No. VA-8300 (Adopted by the Commissioner on August 24, 2018).
[8] COPN Request No. VA-8436.
[9] Chesapeake Hospital Authority d/b/a Chesapeake General Hospital v. State Health Commissioner et. al. (Civil Docket No. CL18-6997)

Table 6. 2017 Adult Open Heart Surgery Volume (VHI Data): PD 20

Facility	Open & Closed Heart Surgery Volume
Bon Secours Maryview Medical Center	789
Sentara Norfolk General Hospital	1,766
Sentara Virginia Beach General Hospital	101
Total	**2,656**
Average	**885.3**

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 178 open-heart procedures in the first year of operation and 268 procedures in the second year. The applicant bases their projections for the first year on 31% of the 582 projected open-heart surgery and TAVR discharges to be generated within CRMC's service area population in 2022. The applicant bases their projections for the second year on 46% of the 587 projected open-heart surgery and TAVR discharges generated within CRMC's service area population. CRMC's projected cases were calculated by applying the incidence rate of open-heart surgery and TAVR discharges in each area to their projected populations.

The applicant states that these cases will generate the necessary procedures without reducing utilization of existing open-heart surgery services in PD 20. In support of this assertion, CRMC erroneously applies the 1600-hour general purpose operating room standard found in 12VAC5-230-500 to show that the operating rooms at SNGH currently exceed the SMFP threshold based on the number of cases reported at that location in 2017. DCOPN finds the use of Need for New Service section of the General Surgical Services section of the SMFP to be inappropriate. If the legislature had intended for utilization of open-heart surgery operating rooms to be evaluated using the same standard as general purpose operating rooms, the legislature would not have created a separate section specific to open-heart surgery.

Moreover, DCOPN finds the assertion that approval of the project will not adversely affect existing providers to be questionable in light of CRMC's assertions above and the vast majority of evidence provided throughout their application. CRMC states that most patients that would receive open-heart surgery at CRMC are forced to travel to receive care at SNGH and provide a great deal of data in support of this assertion. Moreover, the projections provided by CRMC in their application only show a growth of 26 cases in PD 20 between 2018 and 2021, the year in which CRMC expects to open their open-heart program. This number includes TAVR cases as well, which CRMC will not perform in their first year. Their projections max out at 51 additional cases between 2018 and 2024, the last year for which projections were provided by the applicant.

CRMC subsequently submitted additional documentation on December 9, 2019, which included data analysis provided to CRMC by Capital Healthcare Planning. In this report, Capital Healthcare Planning provided projections showing an increase of 110 cases between 2018 and 2023 and 256 cases between 2018 and 2029 using their "population growth" methodology and an increase of 180 cases between 2018 and 2023, and 408 cases between 2018 and 2029 using their "historic trend" methodology. Capital Healthcare Planning additionally stated that there would be minimal impact to Bon Secours Maryview Medical Center as a result of CRMC's open heart surgery program, that Sentara's cardiac surgery program discharges would return to current levels within two years of the start of CRMC's cardiac surgery program, and that Sentara would nonetheless benefit the most from the projected market growth. No data was provided to DCOPN in support of these assertions. As such, DCOPN finds these assertions too speculative to adopt.

Based on the information above, DCOPN finds that it is highly likely that approval of the project would significantly reduce the utilization of existing open-heart surgery services in the health planning district.

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 located 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 applicant does not propose to locate 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.

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. Carver, M.D., FACS as medical director. Dr. Carver 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.

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.

Required Considerations Continued

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.**

   As discussed above, given that CRMC does not perform open-heart surgery within PD 20, approval of the proposed project would foster institutional competition. The Commissioner, however, previously determined that "[f]ostering competition has not historically been a primary objective in regulating highly specialized services such as open heart surgery, the quality and outcomes of which are highly sensitive to patient volume.[10]" As such, DCOPN finds that the facts in relation to this consideration have not materially changed since COPN Request No. VA-8300, and adopts the Commissioner's previous determination that "[i]ncreasing competition in PD 20's provision of open heart surgery would not benefit the area to be served, could harm the quality of care in the area to be served, and would not meaningfully improve access to the service.[11]"

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.**

   As previously discussed, there is not sufficient need for open-heart surgery within the planning district to support the need for a new program at CRMC. Approval of this project will either lead to a low volume program at CRMC, or reduce the volume at the existing open-heart programs. There is a great deal of literature supporting the assertion that there is a direct correlation between higher volumes of open-heart surgery cases at a facility and lessened instances of mortality and morbidity[12]. 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[13]. As in past staff reports[14], DCOPN agrees with the Commissioner's determination and finds that reducing volumes at existing open heart programs past a certain threshold will result in a decrease in the efficiency and quality of existing open heart programs.

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[10] Adjudication Officer's Report, COPN Request No. VA-8300 (Adopted by the Commissioner on August 24, 2018).
[11] *Id.*
[12] See Footnote 2 (p. 5).
[13] Adjudication Officer's Report, COPN Request No. VA-8300 (Adopted by the Commissioner on August 24, 2018).
[14] COPN Request No. VA-8436

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 $6,162,670 (Table 2). This is substantially less than CRMC's previous application for open-heart surgery, which projected costs of $7,853,502. 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 Maryview Medical Center 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. As noted above, DCOPN has adopted the Commissioner determination in Chesapeake's last open-heart application, COPN Request No. VA-8300, that "[i]ncreasing competition in PD 20's provision of open heart surgery would not benefit the area to be served, could harm the quality of care in the area to be served, and would not meaningfully improve access to the service.[15]"

   CRMC states in their application that they anticipate needing 14.0 FTEs for the proposed project. CRMC additionally states that it anticipates the proposed project "should have little impact on the staffing at other facilities..." DCOPN finds the use of "should" in this sentence troubling. Bon Secours, in their letter of opposition, stated that the positions are highly specialized, very competitive and expensive to recruit, and challenging to retain. DCOPN recognizes these difficulties and, in light of these issues, finds that the uncertainty inherent in CRMC's use of the word "should" makes their assertions regarding the effect of the proposed project on other open-heart programs in PD 20 insufficient to show that the proposed project will not adversely affect existing open-heart surgery programs in PD 20. This is especially troubling when existing programs, such as Bon Secours Maryview Medical Center, are struggling with vacancies in several of these critical cardiac positions. As such, DCOPN concludes that approval of the proposed project is likely to have a detrimental effect on staffing at existing open-heart surgery programs in PD 20.

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 new state-of-the-art operating room dedicated to cardiac surgery. The operating room will be built with the latest

[15] *Id.*

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 inconsistent with the applicable criteria and standards of the SMFP and the eight Required Considerations of the Code of Virginia. While recent a court decision has altered DCOPN's interpretation of 12VAC5-230-450(A)(2) in a direction more favorable to the applicant, it also upholds the Commissioner's interpretation of 12VAC5-230-450(A)(1). Under the Commissioner's interpretation of 12VAC5-230-450(A)(1), CRMC fails to meet the threshold necessary to establish a new open-heart service.

Additionally, DCOPN finds that the status quo is a reasonable alternative to the proposed project. Open-heart surgery services are available within a sixty-minute drive, one-way, from over 95% of the population of PD 20. 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. Moreover, approval of the project would be likely to decrease utilization at existing providers of open-heart surgery services or result in a volume at the new program that is below the volume mandated by the SMFP during the first two years of service. This is particularly important, as there is an established connection between high volume open-heart surgery programs and lessened morbidity and mortality with their patients.

Finally, DCOPN finds that approval of the proposed project is likely to have a detrimental effect on staffing at existing open-heart surgery programs in PD 20. Many of the positions required by an open-heart surgery program are highly specialized, very competitive and expensive to recruit, and challenging to retain. Given that existing open-heart surgery programs are struggling with vacancies and that CRMC has offered little explanation in how they intend to acquire the

necessary staff for their program, it is likely that the proposed project would have a detrimental effect on staffing at existing open-heart surgery programs.

DCOPN Staff Recommendations

The Division of Certificate of Public Need recommends the **denial** of Chesapeake Regional Medical Center's COPN Request No. VA-8427 to introduce open-heart surgery at CRMC. DCOPN's recommendation is based on the following findings.

1. The proposal project is not 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 status quo is a reasonable alternative to the proposed project.

3. Approval of the project is likely to decrease utilization at existing providers of open-heart surgery services.

4. Approval of the proposed project is likely to have a detrimental effect on staffing at existing open-heart surgery programs in PD 20.

5. Denial is consistent with the State Health Commissioner's recent decisions for this request from this applicant.