

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

May 19, 2025

COPN Request No. VA-8809

Chesapeake Hospital Authority d/b/a Chesapeake Regional Medical Center
Chesapeake, Virginia
Add one cardiac catheterization laboratory

Applicant

Chesapeake Hospital Authority d/b/a 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; majority owner of Chesapeake Regional Surgery Center, Virginia Beach; and majority 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

According to Virginia Health Information (VHI), there were 18 cardiac catheterization laboratories reported to VHI for PD 20 in 2023, the latest year for which such data are available (**Table 1**). Their utilization equaled diagnostic equivalent procedures (DEPs)¹ of 16,729, 77.4% of the State Medical Facilities Plan (SMFP) standard for increasing the number of cardiac catheterization laboratories (**Table 1**).

¹ "DEP" means diagnostic equivalent procedure, a method for weighing the relative value of various cardiac catheterization procedures as follows: a diagnostic cardiac catheterization equals 1 DEP, a simple therapeutic cardiac catheterization equals 2 DEPs, a same session procedure (diagnostic and simple therapeutic) equals 3 DEPs, and a complex therapeutic cardiac catheterization equals 5 DEPs. A multiplier of 2 will be applied for a pediatric procedure (i.e., a pediatric diagnostic cardiac catheterization equals 2 DEPs, a pediatric simple therapeutic cardiac catheterization equals 4 DEPs, and a pediatric complex therapeutic cardiac catheterization equals 10 DEPs.)

Table 1. PD 20 Cardiac Catheterization Lab Utilization, 2023

Facility Name	# of Labs	Diagnostic	Therapeutic	Same Session	Complex	DEP Total	Utilization Rate
Bon Secours Maryview Medical Center	3	784	27	306	0	1,756	48.8%
Chesapeake Regional Medical Center	2	878	16	405	0	2,125	88.5%
Children's Hospital of The King's Daughters	1	8	23	0	0	108	9.0%
Sentara Leigh Hospital	1	621	3	182	0	1,173	97.8%
Sentara Norfolk General Hospital	6	2,672	331	1,040	235	7,629	106.0%
Sentara Obici Hospital	1	539	1	145	0	976	81.3%
Sentara Princess Anne Hospital	1	392	0	11	0	425	35.4%
Sentara Virginia Beach General Hospital	3	796	133	480	7	2,537	70.5%
Source: 2023 VHI and DCON Calculations	18					16,729	77.4%

Division of Certificate of Public Need (DCOPN) records show that there are now 17 cardiac catheterizations in PD 20 (**Table 2**), one fewer than the number reported to VHI in 2023. COPN Request No. VA- 04814 authorized Bon Secours Maryview Medical Center to utilize cardiac catheterization equipment in an operating room leaving two cardiac catheterization laboratories doing conventional cardiac catheterization.

Table 2. Cardiac Catheterization Laboratory Inventory: 2025

Facility	Cardiac Catheterization Labs
Bon Secours Maryview Medical Center	2
Chesapeake Regional Medical Center	2
Children's Hospital of The King's Daughters	1
Sentara Leigh Hospital	1
Sentara Norfolk General Hospital	6
Sentara Obici Hospital	1
Sentara Princess Anne Hospital	1
Sentara Virginia Beach General Hospital	3
Total	17

Source: DCOPN Records

Proposed Project

CRMC proposes to expand its cardiac catheterization service with the addition of one cardiac catheterization laboratory (its 3rd) in the main hospital at 736 Battlefield Boulevard North, Chesapeake, Virginia, based on institutional need. CRMC has added an open heart surgery program and intends to offer structural heart procedures which require additional cardiac catheterization equipment. The proposed project entails the remodeling/modernization of 1,903 square feet of shell space. Projected capital costs of the project are \$3,752,429 (**Table 3**), funded entirely with CRMC's accumulated reserves such that no financing costs accrue. Should the proposed project be approved, the target date of opening is July 31, 2026.

Table 3. Capital Costs CRMC, Add One Cardiac Cath Lab

Direct Construction Cost	\$ 994,015
Equipment not included in construction contract	\$ 2,659,012
Architectural and Engineering	\$ 99,402
Total Capital Cost	\$ 3,752,429

Source: COPN Request No. VA-8809

Project Definition

Section 32.1.1-102.1 of the Code of Virginia defines a project, in part, as “the addition by an existing medical care facility of any medical equipment for the provision of cardiac catheterization...” 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.**

PD 20 had a population of about 1.2 million in 2020 and is projected to grow by just over 40,000 people, 3.3%, between 2020 and 2030. This is less than the population growth rate projected for Virginia during this decade, 5.8%. Chesapeake City, where the proposed project is located, however, is projected to grow by 9.3%, adding 23,248 people, between 2020 and 2030 (**Table 4**), the highest rate of all localities in PD 20 and higher than that of Virginia. The growth rates projected for 2020-2030 in the 65 and older age group are 41.0% in Chesapeake City and 33.8% in PD 20 overall, compared to 26.3% in Virginia (**Table 4**).

Table 4. PD 20 Population Data

Locality	2020 Census	2030 Projected	Projected Population Change 2020-2030	Projected % Change 2020-2030	2020 65+ Census	2030 65+ Projected	Projected Population Change 65+ 2020-2030	Projected % Change 65+ 2020-2030
Isle of Wight Co.	38,606	41,341	2,735	7.1%	7,751	10,388	2,637	34.0%
Southampton Co.	17,996	17,172	-824	-4.6%	3,719	4,756	1,037	27.9%
Chesapeake City	249,422	272,670	23,248	9.3%	36,045	50,838	14,793	41.0%
Franklin City	8,180	7,667	-513	-6.3%	1,787	1,982	195	10.9%
Norfolk City	238,005	229,864	-8,141	-3.4%	29,215	36,636	7,421	25.4%
Portsmouth City	97,915	98,857	942	1.0%	15,496	19,321	3,825	24.7%
Suffolk City	94,324	102,571	8,247	8.7%	14,708	19,474	4,766	32.4%
Virginia Beach City	459,470	474,052	14,582	3.2%	69,375	94,903	25,528	36.8%
PD 20 Totals	1,203,918	1,244,194	40,276	3.3%	178,096	238,297	60,201	33.8%
Virginia	8,631,393	9,129,002	497,609	5.8%	1,395,291	1,762,641	367,350	26.3%

Source: Weldon-Cooper Data, updated August 2023

With respect to socioeconomic barriers, the poverty rate of PD 20 is higher than that of Virginia (**Table 5**). Chesapeake City, the location of the proposed project has a poverty rate of 8.7%, lower than that of PD 20 and Virginia.

Table 5. 2022 Poverty Rates, PD 20

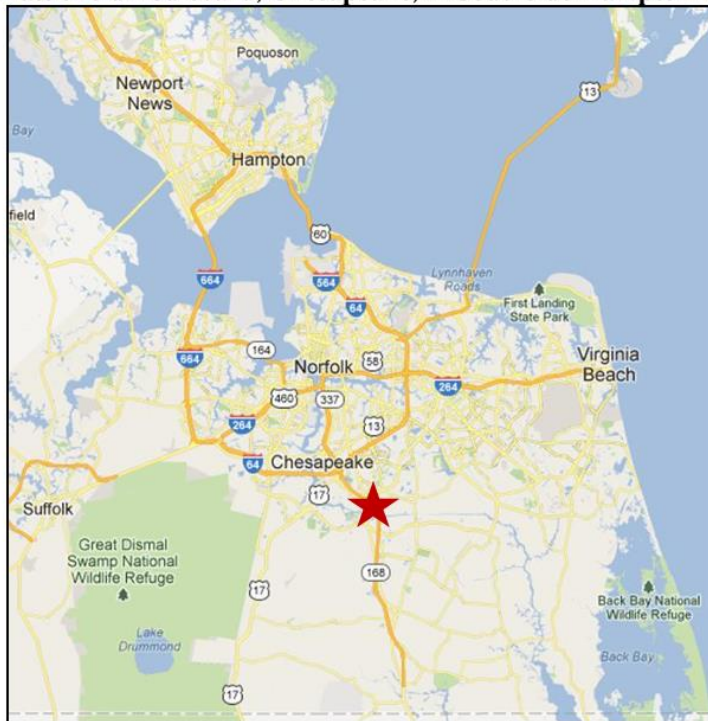
Locality	Percent in Poverty
Isle of Wight County	8.5%
Southampton County	15.0%
Chesapeake City	8.7%
Franklin City	19.0%
Norfolk City	18.8%
Portsmouth City	19.8%
Suffolk City	11.6%
Virginia Beach City	9.9%
PD 20	12.3%
Virginia	10.6%

Source: <https://www.census.gov/data-tools/demo/saipe/#>

The applicant states that CRMC is within one hour's driving time of all residents of PD 20 and portions of northeastern North Carolina. Highway access to the Oak Grove Connector, which feeds into Interstate 64 and Interstate 464, and the Great Bridge Bypass, is within two minutes' driving time from the hospital. Hampton Roads Transit (HRT) provides bus services to the hospital and several taxicab companies operate within the City of Chesapeake. Ambulance services are provided by the Chesapeake Fire Department, volunteer rescue squads in Virginia Beach, commercial medical transport companies and Emergency Medical Services in Dare and

Currituck Counties in North Carolina. Air ambulance services are also provided by Sentara's Nightingale and Emergency Medical Services. The applicant asserts that it is unique in that it serves patients that would otherwise have to travel significant distances to reach other existing facilities, with bridges, tunnels and frequent congestion as travel barriers. CRMC allows patients to receive care within their community.

**Figure 1. Location of Proposed Project and Main Roadways
736 Battlefield Boulevard, Chesapeake, in Southside Hampton Roads**



Source: COPN No. VA-8809

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 a letter of commitment from CRMC's Medical Executive Committee seven letters of support for the proposed project from a cardiac surgeon, interventional cardiologists, an electrophysiologist, CRMC's cardiovascular service line manager and its Chief Medical Officer. These letters, in aggregate, expressed the following:

- The proposed cardiac catheterization laboratory will be a successful addition as it will allow CRMC to continue growing to meet the needs of the community and keep up with advances in health care.
- An additional cardiac catheterization laboratory will allow the hospital to expand its capacity to perform more cardiac catheterization procedures.

- This will improve patient flow and decrease the burden on existing resources.
- This will, in turn, reduce waitlists and patient cancellations and enhance overall quality of care.
- It will also provide flexibility to schedule more procedures and address an increasing volume of specialized procedures, support emergency and elective procedures more efficiently.
- When there is a heart attack, we endeavor to have a door-to-balloon time of less than 60 minutes; however, if the cardiac catheterization laboratory is occupied with an elective complex intervention, then emergency care is delayed with potentially worse patient outcomes.
- I have personally witnessed CRMC's efforts to develop and expand its cardiac program, including adding open heart surgery, as well as growth in its cardiac catheterization volumes.
- These volume increases have created a strain on existing cardiac catheterization laboratories, leading to scheduling difficulties and limiting the ability of CRMC's program to continue to grow in response to residents' needs.
- The proposal will enable better utilization of existing cardiac catheterization laboratories, ensuring the best prioritization of cases.
- Approval of the new cardiac catheterization laboratory is imperative to CRMC's ability to serve patients.
- It is needed to provide more timely care to patients and will allow CRMC's cardiologists to utilize existing cardiac catheterization laboratories more efficiently to perform the more complex cardiac catheterizations performed by cardiologists.
- Growth in the program through the addition of one cardiac catheterization laboratory is consistent with patients' needs and supports growth at its facility.

DCOPN also received a letter of opposition from Bon Secours Hampton Roads Health System (BSHR) making the following points:

- BSHR opposes COPN No. VA-8809.
- CRMC's application contains fundamental errors in its classification of procedures as complex therapeutic cardiac catheterization procedures that result in an overstatement of (DEPs) and invalidate its claim of institutional need for an additional cardiac catheterization laboratory.
- CRMC did not perform an average of 1,200 DEPs per existing cardiac catheterization laboratory for the relevant reporting period.
- CRMC had discussions to determine what qualified as "complex cardiac catheterization" and reclassified procedures to meet a definition that relied on the Society of Cardiovascular Angiography & Interventions (SCAI) which defines PCI therapies for complex interventions.
- This approach is fundamentally incorrect as it relies on a SCAI definition rather than the definition set forth in the SMFP. The SMFP definitions, not the SCAI definition, are what control the assessment of CRMC's cardiac catheterization utilization.
- The SCAI definition includes saphenous vein graft (SVG), unprotected left main (UPLM), bifurcation with severe side branch lesion, severe calcification, chronic total occlusion (CTO), mechanical circulatory support (MCS), coronary thrombosis, three vessel PCI, last remaining conduit or severe tortuosity.
- The SMFP definition focuses on catheter-based procedures for "structural treatment to correct congenital or acquired structural or valvular abnormalities," not complex PCI.
- Complex interventions as referenced by CRMC constitute "simple therapeutic cardiac catheterization" procedures as defined by the SMFP.

- It is incorrect for CRMC to reclassify its historical DEPs based on the SCAI definition rather than the SMFP definition. This results in significant overinflation of complex therapeutic cardiac catheterization procedures.
- The key distinction in the SMFP definitions is based on the anatomical target (coronary arteries versus structural/valvular components).
- SCAI's definition counts all inpatient catheterizations as likely "ACS (acute coronary syndrome)" which are classified by SCAI as complex. "Most myocardial infarctions can be classified as coronary thrombosis, also listed in SCAI's complex category."
- Under the SMFP definition these are categorized as simple therapeutic catheterizations.
- The SCAI definition considers comorbidities, which are not relevant to the SMFP definitions.
- Based on publicly available information and marketing material, CRMC was authorized for its open heart surgery program in 2023 and began performing open heart surgeries in April 2024.
- Open heart backup is required for certain catheter-based structural/vascular procedures which constitute "complex therapeutic catheterization" under the SMFP definitions. CRMC would have been unable to perform complex therapeutic catheterizations in 2023.
- CRMC's 2024 DEPs provided in its application are likely also overinflated if it used the same SCAI methodology.
- CRMC's 2023 data originally reported to VHI provides more accurate and verifiable utilization of cardiac catheterization.
- Its likely inflated DEPs in 2024 still do not achieve the SMFP threshold of 1,200 DEPs per catheterization laboratory.
- CRMC's reliance on the SCAI definition rather than the SMFP categorization method overinflated its DEPs and CRMC does not demonstrate an institutional need for an additional catheterization laboratory.

DCOPN received a response from the applicant to Bon Secours Hampton Roads' letter of opposition that made the following points:

- CRMC appropriately used the SMFP criteria and the SCAI classification to calculate complex therapeutic cardiac catheterizations.
- BSHR noted that the SMFP language broadly defines what constitutes a simple therapeutic cardiac catheterization and a complex cardiac catheterization, but it does not categorize which procedures belong in which category.
- CRMC used both the SMFP definition and SCAI for guidance to clinically group procedures for internal reporting and quality assurance. Case counts on pages 26 and 29 of CRMC's application fully adhere to SMFP definitions for DEP calculations.
- The SMFP's DEP calculation measures the relative value, i.e., resources and time involved in catheterizations.
- Because of changes in technology and clinical practice over the past 7 years, the State Board of Health approved a distinction between simple and complex therapeutic procedures to capture the increased use of cardiac catheterization laboratories for complex therapeutic cases.
- Though the SMFP definition references simple catheterizations to address "coronary artery narrowing" and complex for "structural treatment to correct congenital or acquired structural or valvular abnormalities," it does not provide procedure code definitions.

- VHI instructs providers that it relies on clinical experts within each facility to make those determinations in regard to reporting.
- In the absence of detailed instructions CRMC's reliance on its cardiology experts and their reliance on SCAI's nationally recognized framework is appropriate and reasonable.
- CRMC provided a list of procedures that it counted as complex cardiac procedures for 2023 – 2025:

LIST OF COMPLEX CARDIAC CATHETERIZATION PROCEDURES
IDENTIFIED BY CRMC, FY 2023-2025

Procedure	Hospital Billing Code	CPT code	Description
LM Stent	4819292800	92928	HC PRQ CARD STENT W/ANGIO 1 VSL
Graft Stent	4819293700	92937	HC PRQ REVASC BYP GRAFT 1 VSL
Graft stent additional	4819293800	92938	HC PRQ REVASC BYP GRAFT ADDL
CTO initial vessel	4819294300	92943	HC PRQ CARD REVASC CHRONIC 1VSL
Aortic Valvuloplasty	4819298600	92986	HC PERC BALLOON VALVULOPLASTY; AORTIC VALVE
Atherectomy with Stent Placement	4819293300	92933	HC PRQ CARD STENT/ATH/ANGIO SINGLE
Atherectomy with stent additional	4819293400	92934	HC PRQ CARD STENT/ATH/ANGIO ADDL
Atherectomy with PTCA	4819292400	92924	HC PRQ CARD ANGIO/ATHRECT 1 ART
Atherectomy with PTCA additional	4819292500	92925	HC PRQ CARD ANGIO/ATHRECT ADDL
Mechanical Thrombectomy	4819297300	92973	HC PRQ CORONARY MECH THROMBECT
Shockwave	4819297200	92972	HC PERQ TRULML CORONRY LITHOTRP
IVUS initial	4819297800	92978	HC IVUS INITIAL VESSEL
IVUS additional	4819297900	92979	HC IVUS EACH ADDITIONAL VESSEL
IFR/FFR	4809357100	93571	HC FFR 1ST VESSEL
IABP	3613396700	33967	HC IABP INSERTION
Impella Insertion	3613399000	33990	INSERT PERQ DEVICE ARTERIAL ONLY W/S&I
Impella Repositioning	3613399300	33993	REPOSITION VAD/SEPARATE SESSION W/IMAGING
Impella Removal	3603399200	33992	HC REMOVE VAD DIFFERENT SESSION

Source: SCAI clinical, anatomic and procedural domains of complex PCI, including procedures requiring aspiration catheters or devices, coronary lithotripsy, cutting balloons, covered stents, mechanical circulatory support, intravascular imaging, specialty coronary wires, guide catheter extensions, and embolic protection devices; CRMC cardiac catheterization laboratory case data.

- BSHR contends that CRMC could not have performed complex therapeutic procedures in 2023 as CRMC's open heart program was not operational until April 2024, but that is inaccurate.
- Dr. Ashesh Buch, a CRMC cardiologist and medical director asserts that it is possible within the standard of care to do certain complex cardiac interventional procedures without on-site open heart backup.
- Dr. Buch arrived at CRMC in December 2020 and set up the coronary atherectomy program using orbital atherectomy, proctoring attendings of his and other groups.

- Also, CRMC's cardiovascular interventionalists have performed percutaneous LV support assisted high risk PCI.
- Nearly all CRMC cardiology operators use intracoronary imaging to guide their PCI's which often reveals the need for more complex treatment for better clinical outcomes.
- Since receiving open heart approval, CRMC's interventional cardiologists have performed complex procedures and atherectomy cases no longer need to transfer from CRMC and some chronic total coronary occlusion while its open heart program was under development.
- CRMC intends to treat more chronic total occlusions now that it has open heart surgery to support its catheterization laboratories.
- The argument that CRMC does not need more cardiac catheterization laboratories may have merit if it were not growing with new professional hires, offices and patient throughput.
- Due to changes in technology and clinical practice since 2021, many complex cardiac catheterizations may not require on-site open heart backup. While SMFP states a preference for approving complex therapeutic cardiac catheterizations at hospitals with open heart backup, there is no restriction on their performance if they can be safely performed
- CRMC's project will not adversely affect BSHR or any other cardiac program from its institutional need-based expansion.
- Broader indicators of need support the CRMC Project, such as scheduling delays that impact timely patient care, and population growth, particularly among older adults.
- The modest expansion proposed is essential in maintaining access, improving operational flexibility and supporting the continuum of care for high-acuity cardiac patients.
- CRMC encourages considerations of factors beyond DEP metrics including quality of care, geographic access and integration across service lines.
- CRMC cites prior cardiac catheterization projects at VCU Health (2022) and Bon Secours Maryview (2022) when the regulatory change was recognized but VHI reporting did not include the simple and complex therapeutic distinction until 2023.
- CRMC notes that the addition of a third catheterization laboratory into a hybrid OR was granted without recalculated breakdown of complex or structural cases.
- CRMC's revised 2023, 2024 and projected 2025 DEP volumes far exceed Maryview's 2023 levels when it received COPN approval for its third lab.
- If CRMC's were to dedicate one of its two existing cath labs to complex cases the resulting DEP volume in the remaining lab would far surpass what Maryview demonstrated when it received COPN approval.
- CRMC's institutional need is consistent with past Commissioner decisions to approve cardiac catheterization projects.

DCOPN received another letter from BSHR addressing these points:

- CRMC's response substantiates BSHR's concerns regarding CRMC's failure to categorize cardiac catheterization procedures and calculate DEP volumes consistent with requirements of the SMFP and relevant definitions.

- CRMC acknowledges that it did not adhere to the SMFP-required definitions and instead relied on SCAI classification system. The SMFP definitions do not reference the SCAI classification system and CRMC cannot choose to substitute the SCAI classifications in place of the SMFP definitions just because it wants to.
- By substituting the SCAI classifications for the SMFP definitions, CRMC has created a mechanism to classify more procedures into the more heavily weighted categories of procedures and artificially inflate its DEP calculations, manufacturing an institutional need that does not exist.
- If DCOPN were to accept this approach this would likely trigger additional cardiac catheterization applications across Virginia based solely on this alternative calculation method resulting in a detrimental proliferation of cardiac catheterization laboratories.
- CRMC's assertion that complex therapeutic cardiac catheterization procedures can be performed without open heart surgery backup is not aligned with 12VAC5-230-420 B.
- BSHR maintains its request that DCOPN recommend denial of CRMC's application.

CRMC responded to these arguments with the following:

- BSHR's latest letter was after the public comment period closed.
- BSHR's position remains unsupported and inconsistent with the position it took 4 years ago in adding a cardiac catheterization laboratory at Maryview.
- CRMC did not circumvent SMFP definitions of simple and complex therapeutic cardiac catheterizations. In the absence of detailed information categorizing procedures, CRMC properly relied on classifications developed by SCAI and relied upon by CRMC's cardiology experts.
- With the introduction of interventional cardiology and on-site open heart surgery, CRMC now provides additional complex therapeutic procedures and the SMFP guideline cited by BSHR does not prohibit offering complex catheterizations before open heart surgery backup was available. This is a standard of care decision appropriately made by CMRC's cardiologists.
- Unlike BSHR, CRMC has demonstrated volumes exist that will be served by an additional cardiac catheterization laboratory.
- BSHR has claimed no impact, and CRMC's proposal will relieve delays in patient care that are more extensive than those used to support Bon Secours Maryview cardiac catheterization project in 2021.

Public Hearing

§32.1-102.6B of the Code of Virginia directs DCOPN to hold one public hearing on each application in the case of competing applications; or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. COPN Request No. VA-8809 is not competing with another project and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing was held.

DCOPN provided notice to the public regarding this project inviting public comment on March 10, 2025. The public comment period closed on April 24, 2025. Other than the letters of support and letter of opposition referenced above, no members of the public commented.

(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 because CRMC's application is premature. The recategorization of CRMC's procedures is not consistent with categories set forth in the SMFP and its original reporting to VHI indicates 2,215 DEPs were performed in 2023 in its two cardiac catheterization laboratories, equal to 88.5% of the SMFP threshold for expansion (**Table 1**). Its 2024 DEP volumes, presumably utilizing the same method that over inflated CRMC's revised 2023 DEPs, was 99.6%. These calculations do not yet demonstrate an institutional need for an additional catheterization laboratory. In 2023, PD 20 utilization of cardiac catheterization laboratories was 77.4% of the SMFP threshold indicating adequate cardiac catheterization coverage in PD 20.

(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.

Total projected capital costs for the proposed project are \$3,752,429 of which \$994,015 (26.5%) are direct construction costs (**Table 3**) funded with CRMC's accumulated reserves such that no financing costs accrue. This equates to \$754 per square foot of direct construction costs. The estimated costs are comparable with or lower than other recently approved projects to add a cardiac catheterization laboratory at an acute care facility, COPN No. VA-04891 issued to Inova Fairfax Hospital with a direct construction cost per square foot of \$2,126 and COPN No. VA-04820 issued to Virginia Commonwealth University Health System Authority with direct construction costs per square foot of \$2,539, for example.

The applicant has described several benefits to the proposed project, primarily related to alleviating high utilization, such as reducing wait times for a cardiac catheterization procedure, and addressing growth in demand for cardiac catheterization. The applicant cites heart disease death rates higher than Virginia and national averages and growth in overall population, and specifically over age 45 rates of growth in PD 20 in support of need for an additional cardiac catheterization laboratory. Chesapeake City is projected to have the highest population growth (both rate and population) of localities in PD 20, and higher than that of Virginia. In addition, CRMC intends to offer structural heart procedures, including TAVR which the applicant asserts will require additional cardiac catheterization equipment.

Travel outside of its community is hindered by bridges, tunnels and traffic congestion due to waterways that are geographic boundaries. This is a further incentive for local residents to seek care within Chesapeake.

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

Chesapeake Regional Medical Center provided charity care in the amount of 1.5% in 2023, the latest year for which such data are available. This is slightly lower than the HPR V average of 1.7% (**Table 6**). The proforma provided by the applicant at **Table 8** assumes charity care of 2.5% of gross revenue.

Table 6. Charity Care, HPR V

HPR V	2023 at 200%		
	Gross Pt Rev	Total Charity Care Provided Below 200%	%
Inpatient Hospitals			
Riverside Doctors' Hospital Williamsburg	\$263,828,291	\$8,707,695	3.3%
Riverside Shore Memorial Hospital	\$341,088,652	\$11,224,959	3.3%
Sentara Careplex Hospital	\$1,164,242,503	\$29,652,584	2.5%
Riverside Walter Reed Hospital	\$371,371,717	\$8,973,741	2.4%
Sentara Norfolk General Hospital	\$4,452,208,146	\$105,227,800	2.4%
Sentara Obici Hospital	\$1,273,496,343	\$28,381,455	2.2%
Sentara Leigh Hospital	\$2,031,781,262	\$41,559,157	2.0%
Sentara Virginia Beach General Hospital	\$1,702,923,060	\$33,873,789	2.0%
Riverside Regional Medical Center	\$3,130,814,126	\$60,690,923	1.9%
Chesapeake Regional Medical Center	\$1,267,460,220	\$19,099,394	1.5%
Sentara Princess Anne Hospital	\$1,410,258,179	\$21,159,493	1.5%
VCU Health Tappahannock Hospital	\$207,592,750	\$2,640,231	1.3%
Sentara Williamsburg Regional Medical Center	\$823,825,261	\$10,213,652	1.2%
Virginia Beach Psychiatric Center	\$55,638,150	\$558,000	1.0%
Bon Secours Maryview Medical Center	\$1,459,551,138	\$9,414,682	0.6%
Bon Secours Southampton Medical Center	\$240,211,511	\$1,471,764	0.6%
Newport News Behavioral Health Center	\$32,258,229	\$158,238	0.5%
Bon Secours Mary Immaculate Hospital	\$765,543,060	\$3,588,088	0.5%
Bon Secours Rappahannock General Hospital	\$99,791,350	\$446,763	0.4%
Children's Hospital of the King's Daughters	\$1,437,801,245	\$5,501,594	0.4%
Riverside Rehabilitation Hospital	\$81,843,187	\$287,089	0.4%
Hospital For Extended Recovery	\$32,875,314	\$3,040	0.0%
Select Specialty Hospital-Hampton Roads	\$88,091,051	\$0	0.0%
Kempsville Center for Behavioral Health	\$47,850,285	\$0	0.0%
Lake Taylor Transitional Care Hospital	\$39,571,707	\$0	0.0%
The Pavilion at Williamsburg Place	Did not report	\$0	
Total Inpatient Facilities:			25
HPR V Inpatient Total \$ & Mean%	\$22,821,916,737	\$402,834,131	1.8%

Table 6, continued

Outpatient Centers	Gross Pt Rev	Total Charity Care Provided Below 200%	%
Riverside Peninsula Surgery Center	\$32,371,471	\$1,104,067	3.4%
Careplex Orthopaedic Ambulatory Surgery Center	\$57,325,774	\$1,117,911	2.0%
Sentara BelleHarbour Ambulatory Surgery Center	\$4,884,554	\$87,094	1.8%
Sentara Princess Anne Ambulatory Surgery Management, LLC	\$46,641,017	\$418,450	0.9%
Riverside Hampton Surgery Center	\$35,798,022	\$320,541	0.9%
Riverside Doctors Surgery Center	\$38,415,903	\$263,341	0.7%
CHKD Health & Surgery Center (Newport News)	\$22,661,447	\$57,080	0.3%
Bon Secours Mary Immaculate Ambulatory Surgery Center	\$26,888,307	\$52,606	0.2%
Bon Secours Surgery Center at Virginia Beach	\$45,283,882	\$83,360	0.2%
CHKD Health & Surgery Center (Virginia Beach)	\$40,509,315	\$68,453	0.2%
Sentara Leigh Orthopedic Surgery Center, LLC	\$114,822,981	\$34,520	0.0%
Bon Secours Surgery Center at Harbour View, L.L.C.	\$80,509,018	\$2,834	0.0%
Chesapeake Regional Surgery Center at Virginia Beach, LLC	\$58,862,768	\$0	0.0%
Surgical Suites of Coastal Virginia	\$34,118,670	\$0	0.0%
Sentara Obici Ambulatory Surgery LLC	\$30,297,111	\$0	0.0%
Sentara Virginia Beach Ambulatory Surgery Center	\$24,947,518	\$0	0.0%
Surgery Center of Chesapeake	\$18,080,607	\$0	0.0%
CVP Surgery Center	\$17,501,332	\$0	0.0%
Sentara Port Warwick Surgery Center	\$16,587,877	\$0	0.0%
Center for Visual Surgical Excellence, LLC	\$11,770,965	\$0	0.0%
Bayview Medical Center, Inc	\$4,852,441	\$0	0.0%
Advanced Vision Surgery Center LLC	\$2,109,895	\$0	0.0%
Virginia Center for Eye Surgery			
Total Outpatient Facilities:			22
HPR V Outpatient Total \$ & Mean%	\$ 765,240,875	\$ 3,610,257	0.5%
Total Facilities:			47
HPR V Total \$ & Mean%	\$ 23,587,157,612	\$ 406,444,388	1.7%

Source: 2023 VHI

In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project receive approval, the project would be conditioned to provide a level of charity care based on gross patient revenue, in this case derived from cardiac catheterization services at the proffered 2.5%. Pursuant to Code of Virginia language any COPN issued for this project will also be conditioned on the applicant's agreement to accept patients who are the recipients of Medicare and Medicaid.

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

There are no other factors, not addressed elsewhere in the analysis, relevant to the determination of a public need for the proposed project.

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 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 or expansion of cardiac catheterization services. They are as follows:

Part 1.
Definitions and General Information

12VAC5-230-80. When Institutional Expansion Needed.

A. Notwithstanding any other provisions of this chapter, the commissioner may grant approval for the expansion of services at an existing medical care facility in a health planning district with an excess supply of such services when the proposed expansion can be justified on the basis of a facility's need having exceeded its current service capacity to provide such service or on the geographic remoteness of the facility.

CRMC has two cardiac catheterization laboratories that reported DEP volumes to VHI equal to 88.5% of the SMFP standard in 2023, the latest year for which such data are published. In COPN Request No. VA-8809, the applicant presents DEPs, based on reclassification of its procedures, equal to 105% of the SMFP threshold (**Table 7**). This reclassification is not consistent with definitions of simple and complex therapeutic cardiac catheterizations in the SMFP and shifts procedures into categories with higher DEP multipliers. The SMFP defines complex therapeutic cardiac catheterization as “inpatient visits performed during the reporting period such as catheter-based procedures for structural treatment to correct congenital or acquired structural or valvular abnormalities.” On page 6 of its application, CRMC states that, as part of its open heart program, it intends to offer structural heart procedures, such as TAVR (transaortic valve replacement) acknowledging that it has not offered them in 2023 or 2024.

The applicant includes data for 2024 indicating DEPs at 99.6% of the SMFP standard using the same methodology that shifts procedures into the complex therapeutic category with a multiplier of 5 rather than the (appropriate) simple therapeutic category with a multiplier of 3. CRMC’s original interpretation of cardiac catheterization categories is more consistent with SMFP definitions than the reinterpretation presented in its application to add a cardiac catheterization laboratory.

Table 7. CRMC Utilization 2019-2023

Year	Cath Labs	Diagnostic	Therapeutic	Same Session	Complex	Total DEPs	Utilization
2019	2	557	7	293	0	1,450	60.4%
2020	2	484	4	234	0	1,194	49.8%
2021	2	620	6	346	0	1,670	69.6%
2022	2	785	23	364	0	1,923	80.1%
2023	2	878	16	405	0	2,125	88.5%
2023 (revised)	2	878	6	226	189	2,513	104.7%
2024	2	840	1	236	168	2,390	99.6%

Source: VHI Data (2019-2023) and COPN Request No. VA-8809 (2023 revised and 2024).

CRMC asserts that it is facing delay in patients' accessing cardiac catheterization services, and operational inefficiencies from high utilization that an additional cardiac catheterization will alleviate. In addition, population growth, additional cardiac physicians and resulting demand is likely to increase utilization of cardiac catheterizations further; however, DCOPN concludes that CRMC does not yet meet the DEP threshold to demonstrate institutional need.

B. If a facility with an institutional need to expand is part of a health system, the underutilized services at other facilities within the health system should be reallocated, when appropriate, to the facility with the institutional need to expand before additional services are approved for the applicant. However, underutilized services located at a health system's geographically remote facility may be disregarded when determining institutional need for the proposed project.

Not applicable. CRMC' has no other cardiac catheterization laboratories off site of CRMC.

C. This section is not applicable to nursing facilities pursuant to § 32.1-102.3:2 of the Code of Virginia.

Not applicable. The applicant is not a nursing facility.

D. Applicants shall not use this section to justify a need to establish new services.

Not applicable. The applicant is an existing provider of cardiac catheterization services in PD 20.

- 1. Existing fixed site cardiac catheterization services located in the health planning district performed an average of 1,200 cardiac catheterization DEPs per existing and approved laboratory for the relevant reporting period;**
- 2. The proposed new service will perform an average of 200 DEPs in the first year of operation and 500 DEPs in the second year of operation;**

3. The utilization of existing services in the health planning district will not be significantly reduced.

Not applicable, but for context, DCOPN has calculated cardiac catheterization laboratory need:

Calculated Needed Fixed CT Scanners in PD 20

COPN authorized cardiac catheterization labs = 17

Calculated cardiac catheterization labs needed in PD 20 =

16,729 DEPs in the PD (**Table 1**) / 1,200 DEPs / cardiac catheterization lab = 13.94 (14) cardiac catheterization labs needed

PD 20 Calculated Need = 14 cardiac catheterization labs

PD 20 Calculated Surplus = 3 cardiac catheterization labs

In 2023, the last year for which DCOPN has data available from VHI, the existing fixed cardiac catheterization labs in PD 20 operated at 77.4% of the SMFP threshold mandated by this section (**Table 1**). Based on this utilization in the planning district, DCOPN calculated a regional need, in 2023, for 14 cardiac catheterization labs in PD 20. As there are currently 17 cardiac catheterization labs in PD 20, DCOPN calculates a surplus of 3 cardiac catheterization labs. As the applicant is an existing provider of cardiac catheterization services, these calculations are presented to provide an overview of cardiac catheterization services in the planning district.

B. Proposals for mobile cardiac catheterization laboratories should be approved only if such laboratories will be provided at a site located on the campus of an inpatient hospital. Additionally, applicants for proposed mobile cardiac catheterization laboratories shall be able to project that they will perform an average of 200 DEPs in the first year of operation and 350 DEPs in the second year of operation without significantly reducing the utilization of existing laboratories in the health planning district below 1,200 procedures.

Not applicable. The proposed project is not for a mobile cardiac catheterization laboratory.

C. Preference may be given to a project that locates new cardiac catheterization services at an inpatient hospital that is 60 minutes or more driving time one way under normal conditions from existing services if the applicant can demonstrate that the proposed new laboratory will perform an average of 200 DEPs in the first year of operation and 400 DEPs in the second year of operation without significantly reducing the utilization of existing laboratories in the health planning district.

Not applicable. The proposed project seeks to expand an existing cardiac catheterization program.

12 VAC 5-230-400. Expansion of Services.

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

- A. All existing cardiac catheterization laboratories operated by the applicant's facilities where the proposed expansion is to occur have performed an average of 1,200 DEPs per existing and approved laboratory for the relevant reporting period; and**

CRMC has two cardiac catheterization laboratories that reported DEP volumes to VHI equal to 88.5% of the SMFP standard in 2023, the latest year for which such data are published. In COPN Request No. VA-8809, the applicant presents DEPs, based on reclassification of its procedures from 2023, equal to 105% of the SMFP threshold. This reclassification is not consistent with definitions of simple and complex therapeutic cardiac catheterizations and shifts procedures into categories with higher DEP multipliers. The applicant includes data for 2024 indicating DEPs at 99.6% of the SMFP standard using the same methodology that shifts nonstructural procedures into higher categories than the SMFP definitions describe.

- B. The applicant can demonstrate that the expanded service will achieve an average of 200 DEPs per laboratory in the first 12 months of operation and 400 DEPs in the second 12 months of operation without significantly reducing the utilization of existing cardiac catheterization laboratories in the health planning district.**

Due to population growth and aging, the addition of cardiac physicians and the addition of structural heart procedures, the applicant credibly projects the proposed laboratory would perform 210 DEPs in Year 1 and 561 DEPs in Year 2, volumes over the thresholds given in this section.

12 VAC 5-230-410. Pediatric Cardiac Catheterization.

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

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

Not applicable. The applicant is not proposing to provide pediatric cardiac catheterization procedures.

12VAC5-230-420. Non-emergent Cardiac Catheterization.

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

The programs shall:

- 1. Participate in the Virginia Heart Attack Coalition, the Virginia Cardiac Services Quality Initiative, and the Action Registry-Get with the Guidelines or National Cardiovascular Data Registry to monitor quality and outcomes;**

2. Adhere to strict patient-selection criteria;
3. Perform annual institutional volumes of 300 cardiac catheterization procedures, of which at least 75 should be percutaneous coronary intervention (PCI) or as dictated by American College of Cardiology (ACC)/American Heart Association (AHA) Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories effective 1991;
4. Use only AHA/ACC-qualified operators who meet the standards for training and competency;
5. Demonstrate appropriate planning for program development and complete both a primary PCI development program and an elective PCI development program that includes routine care process and case selection review;
6. Develop and maintain a quality and error management program;
7. Provide PCI 24 hours a day, seven days a week;
8. Develop and maintain necessary agreements with a tertiary facility that must agree to accept emergent and nonemergent transfers for additional medical care, cardiac surgery, or intervention; and
9. Develop and maintain agreements with an ambulance service capable of advanced life support and intra-aortic balloon pump transfer that guarantees a 30-minute or less response time.

B. Complex therapeutic cardiac catheterization. Proposals to provide complex therapeutic cardiac catheterization should be approved only when open heart surgery services are available on-site in the same hospital in which the proposed complex therapeutic service will be located. Additionally, these complex therapeutic cardiac catheterization programs will be required to participate in the Virginia Cardiac Services Quality Initiative and the Virginia Heart Attack Coalition.

In response to this section, the enumerated requirements of part A are not addressed specifically. The applicant states that “[O]pen heart surgery services are available on site and CRMC has had great successes and has developed its program in a short time to a high-quality, reliable service for PD 20 residents seeking open heart surgery services. As a result, interventional cardiac procedures may be performed at CRMC based on SMFP and SCAI standards.”

12 VAC 5-230-430. Staffing.

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

CRMC provided assurances that cardiac catheterization services are under the direction of a medical director with the required board certification and experience.

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

Not applicable. CRMC is not proposing to perform pediatric cardiac catheterization procedures.

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

CRMC provided assurances that cardiac catheterization services are under the direction of a medical director with the required board certification and experience.

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

Not applicable. CRMC is not proposing to perform pediatric cardiac catheterization procedures.

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.**

The proposal is intended to serve patient already seeking care at CRMC and does not foster institutional competition.

- 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, DCOPN has calculated a net surplus of 3 cardiac catheterization laboratories in PD 20. If approved, the proposed project would add to the surplus. The applicant has not demonstrated that its redistribution of procedures reported in 2023 that yielded a higher DEP count than originally reported is appropriate or consistent with the categories laid out in the SMFP. CRMC has not demonstrated institutional need to expand. The applicant is part of the Chesapeake Hospital Authority Parent Company, which has no other facilities offering cardiac catheterization in PD 20.

- 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.**

Projected capital costs of \$3,752,429 (**Table 3**) are reasonable when compared to other recently authorized and similar projects. The proposal will be funded entirely with CRMC's accumulated reserves such that no financing costs accrue. The proforma income statement provided by the applicant projects net income before taxes of \$618,103 in the first year of operation, and \$1,030,173 in the second year of operation (**Table 8**).

With regard to staffing, the applicant states that the proposed project requires only four additional full-time equivalent staff members. This number is feasible to recruit. DCOPN notes that the hospital as a whole has 215 vacancies of 1,751 FTEs (12.3%).

Table 8. Proforma, Add one Cardiac Cath Lab at CRMC

	Year 1	Year 2
Revenue	\$ 5,834,193	\$ 9,723,655
Charity Care	\$ 145,855	\$ 243,091
Other Deductions	\$ 3,951,759	\$ 6,586,265
Total Net Revenue (net Charity Care)	\$ 1,736,579	\$ 2,894,299
Total Expenses	\$ 1,118,476	\$ 1,864,126
Net Income Before Taxes	\$ 618,103	\$ 1,030,173

Source: COPN Request No. VA-8809

- 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.**

The proposal does not provide innovation in the delivery of health services nor the delivery of care in an outpatient facility.

- 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 associated with a public institution of higher education or a medical school in the area to be served.

DCOPN Staff Findings and Conclusions

The proposed project is in an area of the Commonwealth experiencing high growth. It has support from the medical staff at CRMC but also has documented opposition. CRMC has not yet demonstrated institutional need for the project. It is premature. The status quo is a reasonable alternative to the proposed project that would meet the needs of the population in a less costly, more efficient, or more effective manner. Costs of the proposal are reasonable and wholly feasible.

DCOPN finds that Chesapeake Hospital Authority d/b/a Chesapeake Regional Medical Center's COPN Request Number VA-8809 to add one cardiac catheterization laboratory is inconsistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia.

DCOPN Staff Recommendations

The Division of Certificate of Public Need recommends **denial** of Chesapeake Hospital Authority d/b/a Chesapeake Regional Medical Center's COPN Request Number VA-8809 to add one cardiac catheterization laboratory in its hospital facility in Chesapeake, Virginia for the following reasons:

1. The proposal to add one cardiac catheterization laboratory at Chesapeake Hospital Authority d/b/a Chesapeake Regional Medical Center is inconsistent with the applicable standards and criteria of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.
2. The applicant has not demonstrated an institutional specific need for cardiac catheterization capacity, so the proposal is premature.
3. There is documented opposition to the proposed project.

Should the Commissioner decide to approve COPN Request No. VA-8809, Chesapeake Hospital Authority d/b/a Chesapeake Regional Medical Center must accept the following charity care condition:

Chesapeake Hospital Authority d/b/a Chesapeake Regional Medical Center will provide cardiac catheterization 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 Hospital Authority d/b/a Chesapeake Regional Medical Center's gross patient revenue derived from cardiac catheterization 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 Hospital Authority d/b/a 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 Hospital Authority d/b/a Chesapeake Regional Medical Center will provide cardiac catheterization services to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et

seq.), and 10 U.S.C. § 1071 et seq. Additionally, Chesapeake Hospital Authority d/b/a 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.