VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

May 19, 2022

COPN Request No. VA-8620
Maryview Hospital LLC, d/b/a Bon Secours Maryview Medical Center
Portsmouth, Virginia
Expand cardiac catheterization services by adding cardiac catheterization equipment into the hospital's hybrid operating room

Applicant

Bon Secours Hampton Roads Health System, Inc. (BSHR) is the sole corporate member of Maryview Hospital d/b/a Maryview Medical Center (Maryview). BSHR and Maryview are both 501(c)(3) not-for-profit, non-stock corporations in Virginia. Maryview currently provides services on its campus in downtown Portsmouth and on its campus in northern Suffolk, Bon Secours Harbour View. Both of Maryview's campuses are in Health Planning Region (HPR) V, Planning District (PD) 20.

Background

Maryview is a 346-bed-not-for-profit, acute care hospital with a main campus located in Portsmouth, Virginia. The hospital provides a comprehensive array of inpatient and outpatient tertiary services, including but not limited to cardiovascular services, surgery, behavioral medicine services, orthopedics, oncology and acute rehabilitation.

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the "[i]ntroduction into an existing medical care facility described in subsection A of any cardiac catheterization…when such medical care facility has not provided such service in the previous 12 months." In stating such, the Code of Virginia puts the requirement that a COPN authorized service is provided within the previous 12 months for it to remain authorized. On October 7, 2021, in response to questions from DCOPN, BSHR stated that:

> "Effective April 1, 2021, Maryview closed the facility known as Bon Secours DePaul Medical Center as an inpatient acute care hospital. Maryview, as the surviving entity from the merger, continues to operate certain services on the former DePaul campus in Norfolk, as Maryview outpatient services. Such services include imaging (including mammography, nuclear camera, and mobile PET/CT services), radiation oncology services (2 linear accelerators, a CT simulator, and brachytherapy services), and certain other non-regulated services…. As you know, under the COPN law and regulations, Maryview has the right within 12 months following the April 1, 2021 closure of inpatient services at DePaul to re-commence the provision of services without COPN review or approval being required. This is sometimes

> referred to colloquially as "the 12 month rule." Without waiving any COPN rights that Maryview retains under the 12-month rule, the following COPN-regulated services are not currently in operation on the DePaul campus: …. cardiac catheterization services (1 cardiac cath laboratory)."

In review of the application, DCOPN requested that Maryview clarify the last date on which the cardiac catheterization lab at DePaul was last used. The applicant responded stating that "[c]ardiac catheterization services were available at Bon Secours DePaul Medical Center ("DePaul") until March 22, 2021. The facility ceased inpatient operations on April 1, 2021." Based on the Code of Virginia, as well as the applicant's own admission regarding the "12 month rule," the COPN authorized cardiac cauterization lab at DePaul no longer exists

According to the 2020 Virginia Health Information (VHI) data, the most recent year for which such data is available, and DCOPN records, there are 18 stationary cardiac catheterization laboratories in PD 20 (**Table 1**). As shown in **Table 8** below, Maryview's two cardiac catheterization labs operated at 53.7% of the State Medical Facilities Plan (SMFP) threshold detailed in 12 VAC 5-230-400. As shown in **Table 6** below, Maryview's utilization has remained basically flat for the prior four years.

Table 1. Cardiac Catheterization Laboratory Inventory: 2022

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

Maryview proposes to relocate a cardiac catheterization lab from DePaul Medical Center (DePaul) to a hybrid operating room at Maryview. The applicant asserts that the projected capital costs of the proposed project total $5,000, the entirety of which will be funded using the accumulated reserves of the applicant (**Table 2**). Accordingly, there are no financing costs associated with this project. Regarding these costs, the applicant asserts that the majority of the costs of the proposed project are covered by the VA-R-06-22, issued on 1/17/22, which proposed to replace one of the two COPN authorized cardiac catheterization labs at Maryview and move it into a hybrid operating room in conjunction with a General Electric Allia IGS 740 HOR angiography system that is cardiac catheterization-capable. The accuracy of these assertions are discussed with the costs of the project below. The applicant anticipates an opening date in October 2022.

Table 2. Maryview Projected Capital Costs

Equipment Not Included in Construction Contract	$5,000
Total Capital Costs	**$5,000**

Source: COPN Request No. VA-8620

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

Maryview proposes to relocate an existing cardiac catheterization lab from DePaul Medical Center to a hybrid operating room at Maryview. As discussed above, no COPN authorized cardiac catheterization lab exists at DePaul, as it has not been utilized for over 12 months. The applicant asserts that the relocation of the cardiac catheterization lab is necessary for Maryview to begin offering catheter-based cardiac surgeries. The applicant additionally states that installation of the new cardiac catheterization equipment will allow for ST-elevation myocardial infarction (STEMI) procedures without the need for the patient to be removed from the operating table. The applicant finally states that Maryview would be "the first hospital in Western Hampton Roads to offer this service, and thus will improve access to advanced cardiac services for its patient population, without requiring travel to Norfolk, Virginia Beach, or facilities in PD 21 from Western Hampton Roads through high rise bridges, draw bridges, or tolled bridge tunnels ($2.50 each way during peak hours) that are often congested." DCOPN notes that Sentara Norfolk General Hospital, which has a hybrid operating room used for advanced cardiac procedures, is located 4.1 miles from the applicant.

Geographically, Maryview is located on U.S. 17, and is accessible from I-264 and SR-164 via exits approximately 1.2 miles from the campus. The applicant asserts that excellent bus service exists for the hospital and its patients. DCOPN identified two stops, one approximately 0.2 miles from Maryview, and one approximately 0.8 miles from Maryview. The applicant does not address any benefits or drawbacks regarding public parking at Maryview.

Weldon-Cooper data projects a total PD 20 population of 1,255,394 residents by 2030 (**Table 3**), which represents an approximate 9.6% increase in total population from 2010 to 2030. This is a much smaller percentage increase than the total for Virginia, which will increase by approximately 16.6% for the same period. With regard to the City of Portsmouth, where Maryview is located, specifically, Weldon-Cooper projects a total population decrease of 4,820, or approximately a 5% decrease from 2010 to 2030. DCOPN notes this decrease is projected to occur nearly entirely in the period between 2020 and 2030. Portsmouth City is the sole area in PD 20 with a population above 20,000 that is projected to experience a decrease in total population during this period.

With regard to the 65 and older age cohort, Weldon-Cooper projects a total PD 20 population of 175,194 by 2030 (**Table 4**), which represents an approximate 73.4% increase in the population within that age cohort from 2010 to 2030. This is a slightly lower percentage increase than the total for Virginia, which will increase by approximately 76.4% for the same period. With regard to the City of Portsmouth specifically, Weldon-Cooper projects a population increase in this age cohort of 4,125, or approximately 32.7% from 2010 to 2030. This total population increase is sixth among the eight areas listed in **Table 4**, and seventh in percentage increase among the eight areas listed.

Table 3. PD 20 and Statewide Total Population Projections, 2010-2030

Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Chesapeake City	222,209	249,244	12.2%	270,506	8.5%	21.7%
Franklin City	8,582	8,268	-3.7%	8,140	-1.6%	-5.2%
Isle of Wight	35,270	38,060	7.9%	41,823	9.9%	18.6%
Norfolk City	242,803	246,881	1.7%	249,889	1.2%	2.9%
Portsmouth City	95,535	95,027	-0.5%	90,715	-4.5%	-5.0%
Southampton	18,570	17,739	-4.5%	17,711	-0.2%	-4.6%
Suffolk City	84,585	94,733	12.0%	109,424	15.5%	29.4%
Virginia Beach City	437,994	457,699	4.5%	467,187	2.1%	6.7%
Total PD 20	**1,145,548**	**1,207,652**	**5.4%**	**1,255,394**	**4.0%**	**9.6%**
Virginia	8,001,024	8,655,021	8.2%	9,331,666	7.8%	16.6%

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

Table 4. PD 20 Population Projections for 65+ Age Cohort, 2010-2030

Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Chesapeake City	23,146	33,439	44.5%	47,651	42.5%	105.9%
Franklin City	1,480	1,663	12.3%	1,781	7.1%	20.4%
Isle of Wight	5,165	7,759	50.2%	10,944	41.1%	111.9%
Norfolk City	22,796	27,013	18.5%	33,488	24.0%	46.9%
Portsmouth City	12,619	14,225	12.7%	16,744	17.7%	32.7%
Southampton	2,828	3,669	29.7%	4,842	32.0%	71.2%
Suffolk City	9,727	14,656	50.7%	20,626	40.7%	112.0%
Virginia Beach City	46,435	65,468	41.0%	86,768	32.5%	86.9%
Total PD 20	**101,050**	**134,453**	**33.1%**	**175,194**	**30.3%**	**73.4%**
Virginia	976,937	1,352,448	38.4%	1,723,382	27.4%	76.4%

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

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

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

DCOPN received 27 letters of support from all members of the Bon Secours Hampton Roads Board of Directors, one member of the public, and several physicians associated with Bon Secours. Collectively, these letters articulated the high mortality rate associated with heart disease nationally, within the Commonwealth, and regionally. The letters additionally state that this area has a substantially increasing senior population. DCOPN notes that **Table 4**, above, does not reflect this assertion. Finally, the letters assert that there is a need for both cardiac

catheterization labs as well as the hybrid operating room. DCOPN did not receive any letters in opposition to the proposed project.

Public Hearing
DCOPN provided notice to the public regarding this project on March 10, 2022. The public comment period closed on April 25, 2022. Section 32.1-102.6 B of the Code of Virginia directs DCOPN to hold one public hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city in the case of competing applications; or in response to a written request by an elected local government representative, a member of the General Assembly, the Virginia State Health Commissioner (Commissioner), the applicant, or a member of the public. The proposed project is not competing, and no public hearing was requested by the applicant, the Commissioner, an interested party, or member of the public. As such, no public hearing was held.

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

The status quo is a preferable alternative to the proposed project. As stated above, the cardiac catheterization lab at DePaul ceased to exist under the Code of Virginia following its inactivity over the past year. As such, no cardiac catheterization lab exists to relocate for the proposed project. As the proposed project cannot be effectuated, the status quo remains a de facto necessary alternative to the proposed project.

Additionally, there is not a need, in the planning district, or at Maryview, for an additional cardiac catheterization lab to be added. As discussed in DCOPN's analysis of 12VAC5-230-80 below, analysis of all available objective data led DCOPN to conclude that Maryview's cardiac catheterization procedure levels have remained static for the past five years. Moreover, DCOPN calculations pursuant to 12VAC5-230-390 below show a calculated surplus of four cardiac catheterization labs in the planning district. As such, approval of the proposed project would introduce a new cardiac catheterization lab into an area that already has a surplus equivalent to approximately 23.5% of the total cardiac catheterization lab inventory for PD 20.

Under the status quo, the applicant could choose to complete the project using the previously discussed equipment that was moved into its hybrid OR, should a sufficient need exist. If a sufficient volume does not exist, a facility that performs these advanced cardiac procedures in a hybrid operating room is located a mere 4.1 miles from the applicant. Given the current volume of the existing cardiac catheterization labs reported to VHI, 53.7% in 2020 (**Table 6**), the applicant should have no issue utilizing the two labs to address the current needs of their patients. Moreover, as shown in **Table 6** below, Maryview's utilization has remained basically flat for the prior four years. As such, sufficient capacity should exist even with the applicant not using the relocated cardiac catheterization lab equipment for diagnostic procedures.

For the reasons discussed above reasons, DCOPN concludes that the status quo is a preferable alternative to the proposed project.

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

Currently there is no organization in HPR 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 proposed project;

The applicant asserts that the projected capital costs of the proposed project total $5,000 (**Table 2**), which would be funded using the applicant's accumulated reserves. Accordingly, there are no financing costs associated with this project. As discussed above, the applicant asserts that the majority of the costs of the proposed project are covered by VA-R-06-22, issued on 1/17/22, which proposed to replace one of the two COPN authorized cardiac catheterization labs at Maryview and move it into a hybrid operating room in conjunction with a General Electric Allia IGS 740 HOR angiography system that is cardiac catheterization-capable. DCOPN disagrees with this assertion. The approved costs for VA-R-06-22 cover the project contemplated within that registration. Maryview additionally asserted in their application that the opening date for the hybrid operating room would occur prior to the issuance of the requested certificate and one of the two existing Maryview cardiac catheterization labs being taken out of service until a certificate was issued for this project. Based on the costs associated and projected opening date, DCOPN reached out to the applicant to clarify if the proposed project did not, instead, represent the request to relocate the alleged DePaul cardiac catheterization lab to replace the cardiac catheterization lab relocated as part of VA-R-06-22. The applicant once more confirmed that they would not be moving forward with VA-R-06-22 and would instead be seeking to relocate the alleged DePaul cardiac catheterization lab to the hybrid operating room at Maryview. As the applicant is not proceeding with VA-R-06-22, the applicant's use of the expenses of this registration to cover this project are not appropriate. COPN precedent does not support this activity and effectively opens the door for applicants to utilize the registration process to circumvent the Code of Virginia. This is especially concerning as, coupled with the exemption provided to hospitals regarding registration cost caps, this method of circumventing the statutorily mandated fee structure would more heavily benefit hospitals over the non-hospital affiliated physician. As the applicant's stated costs for the project are clearly erroneous, DCOPN finds the costs of the project too speculative to address in this staff report. As such, DCOPN is forced to conclude that the costs of the project are unreasonable. As discussed above, DCOPN ultimately concludes that the proposed project does not offer any benefits that could not be effectuated better through the maintenance of the status quo.

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

As **Table 5** below demonstrates, Maryview provided 1.92% of its gross patient revenue in the form of charity care in 2020. This is below the HPR V regional average of 2.5% for the same period. In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project be approved, Maryview is expected to provide a level of charity care consistent with its system-wide condition.

Table 5: HPR V 2020 Charity Care Contributions

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

Source: VHI

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

DCOPN did not identify any other discretionary factors, not discussed elsewhere in this staff analysis report, to bring to the attention of the Commissioner as may be relevant to determining a public need for the proposed project.

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

Section 32.1-102.2:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop, by November 1, 2022, recommendations for a comprehensive State Health Services Plan (SHSP). In the interim, these regulations provide the best available criteria and 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.

As detailed in **Table 6** below, the utilization of Maryview's two cardiac catheterization labs has remained consistent, with the exception of the drop in 2017, since 2016. Maryview asserts that there has been a steady increase in the utilization of the catheterization labs and provided the data detailed in **Table 7** below, but not reported to Virginia Health Information. DCOPN finds this assertion suspect. The addition of these complex therapeutic catheterization procedures are not represented anywhere in the VHI data. Moreover, these unverifiable procedures are the sole reason that the cardiac catheterization labs at Maryview show any sort of material growth. As the data is suspiciously convenient to the applicant's narrative and completely unverifiable through available impartial data, DCOPN cannot adopt this data. Even were this data accepted, the applicant falls well below the necessary threshold to show institutional need to expand its cardiac catheterization services. For the reasons discussed above, DCOPN concludes that the applicant does not meet this threshold.

As discussed above, the applicant additionally asserts that an institutional need would exist when one cardiac catheterization lab is relocated to the hybrid operating room. However, as stated previously, given the utilization shown in the objective VHI data, there appears to be ample capacity to address this need using the two existing cardiac catheterization labs, even with the limitations intended by the applicant. Additionally, rewarding an applicant for creating an institutional need through limiting the use of a medical resource would run contrary to the intent of the SMFP. As such, DCOPN concludes that the applicant does not meet this threshold.

Table 6. Maryview Utilization 2016-2020

Year	Cath Labs	Diagnostic	Therapeutic	Same Session	Total DEPs	Utilization
2016	2	439	17	259	1,250	52.1%
2017	2	386	23	228	1,116	46.5%
2018	2	459	6	262	1,257	52.4%
2019	2	516	25	234	1,268	52.8%
2020	2	540	11	242	1,288	53.7%

Source: VHI Data (2016-2020)

Table 7. Maryview Utilization 2017-2021 (Applicant's Assertion)

Year	Cath Labs	Diagnostic	Therapeutic	Same Session	Complex Therapeutic	Total DEPs	Utilization
2017	2	386	23	228	80	1,516	63.2%
2018	2	459	6	262	72	1,617	67.4%
2019	2	516	25	234	84	1,688	70.3%
2020	2	540	11	242	71	1,643	68.5%
2021	2	619	56	197	109	1,867	77.8%

Source: COPN Request No. VA-8620

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.

As the applicant has failed to establish an institutional need to expand its cardiac catheterization program, this section is not applicable to the proposed project. However, were the applicant to have established an institutional need to expand its services, no underutilized cardiac catheterization labs within the Bon Secours Health System are available in the planning district to relocate to meet this need. Maryview remains the sole Bon Secours Health System location within the planning district following the closure of DePaul. As discussed in detail above, the cardiac catheterization lab at DePaul is no longer authorized by a certificate of public need.

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.

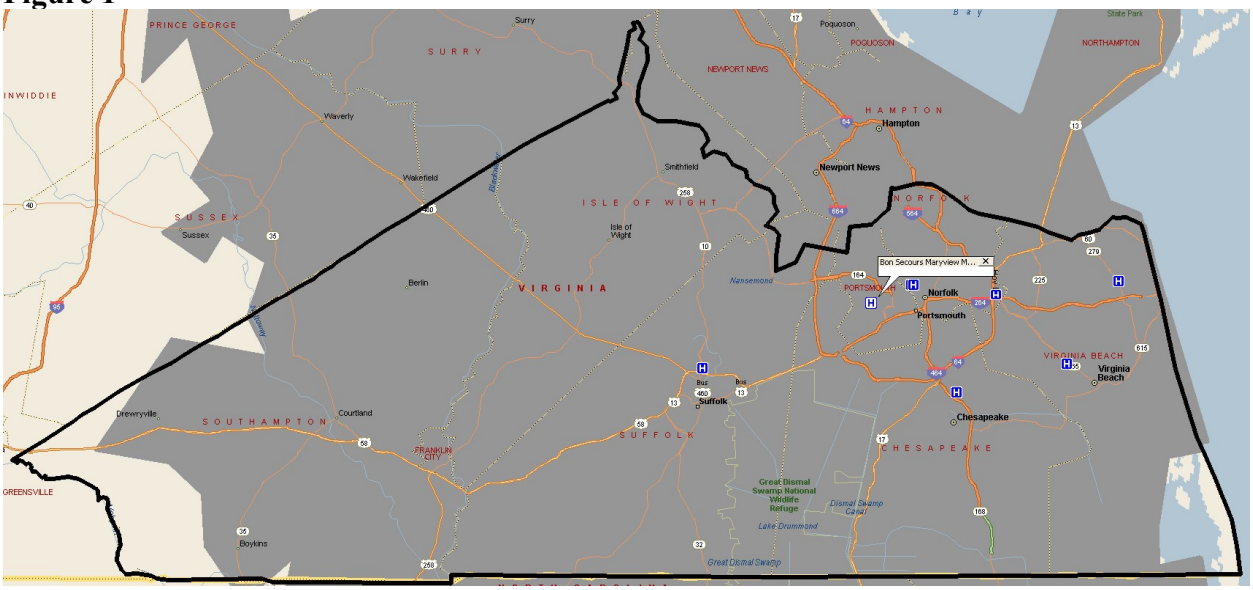
Not applicable. The applicant is an existing provider of cardiac catheterization services in PD 20.

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

12 VAC 5-230-380. Travel Time.
Cardiac catheterization services should be within 60 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the Commissioner.

The heavy dark line in **Figure 1** identifies the boundaries of PD 20. In **Figure 1**, the grey shading illustrates the area that is within 60 minutes driving time one way under normal driving conditions of all cardiac catheterization service providers in PD 20. As the two unshaded areas of Figure 1 are located in a low population area of the planning district, and is relatively small, DCOPN concludes that 95% of the population of PD 20 are currently within 60 minutes driving time one way under normal traffic conditions of cardiac catheterization services.

Figure 1



12 VAC 5-230-390. Need for New Service.

A. No new fixed site cardiac catheterization service should be approved for a health planning district unless:

1. **Existing fixed site cardiac catheterization services located in the health planning district performed an average of 1,200 cardiac catheterization DEPs per existing and approved laboratory for the relevant reporting period;**
2. **The proposed new service will perform an average of 200 DEPs in the first year of operation and 500 DEPs in the second year of operation;**
3. **The utilization of existing services in the health planning district will not be significantly reduced.**

Calculated Needed Fixed CT Scanners in PD 20
COPN authorized cardiac catheterization labs = 17

Calculated needed cardiac catheterization labs =
14,449 DEPs in the PD / 1,200 DEPs / cardiac catheterization lab = 12.04 (13) cardiac catheterization labs needed

PD 20 Calculated Need = 13 cardiac catheterization labs

PD 20 Calculated Surplus = 4 cardiac catheterization labs

In 2020, the last year for which DCOPN has data available from VHI, the existing fixed cardiac catheterization labs in PD 20 operated at 66.9% of the SMFP threshold mandated by this section (**Table 8**). Based on this utilization in the planning district, DCOPN calculated a regional need, in 2020, for 13 cardiac catheterization labs in PD 20. As there are currently 17 cardiac catheterization labs in PD 20, DCOPN calculates a surplus of 4 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.

Table 8. PD 20 Cardiac Catheterization Utilization (in DEPs) (2020)

	# of Labs	Diagnostic	Therapeutic	Same Session	Total DEPs[1]	Utilization Rate
Bon Secours DePaul Medical Center[2]	1	100	1	58	276	23.0%
Bon Secours Maryview Medical Cntr	2	540	11	242	1,288	53.7%
Chesapeake Regional Medical Center	2	484	4	234	1,194	49.8%
Children's Hospital of The King's Daughters	1	48	171	0	390	32.5%
Sentara Leigh Hospital	1	439	1	174	963	80.3%
Sentara Norfolk General Hospital	6	2,680	510	996	6,688	92.9%
Sentara Obici Hospital	1	477	0	108	801	66.8%
Sentara Princess Anne Hospital	1	372	0	8	396	33.0%
Sentara Virginia Beach General Hospital	3	717	133	490	2,453	68.1%
2020 Total and Average	**18**	**5,857**	**831**	**2,310**	**14,449**	**66.9%**

Source: VHI

B. Proposals for mobile cardiac catheterization 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 seeks to expand an existing cardiac catheterization program.

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.

[1] 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).
[2] Closed in 2021.

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

The applicant states this standard does not apply to the proposed project. DCOPN disagrees with this assertion. No exception is made in the language of the SMFP to differentiate between the expansion of an existing service through the relocation of previously approved cardiac catheterization lab and the expansion of an existing service through the addition of a new cardiac catheterization lab. As the relocation of existing underutilized services is an additional consideration in the section of the SMFP governing institutional need[3], rather than an alternative, there is no reason for the applicant to interpret relocation as an alternative to meeting the necessary threshold here. Moreover, the application of this standard to the relocation of an existing service is vital in determining if a need exists for the relocated cardiac catheterization lab at the proposed location, or if the relocation would exacerbate the underutilization of the relocated cardiac catheterization lab.

In this case, this matter is moot. As discussed above, a COPN authorized cardiac catheterization lab no longer exists at DePaul after it has laid fallow for over a year after cardiac catheterization services ceased to be available on March 22, 2021 when DePaul closed. As the project, under its current scope, is impossible to effectuate, the applicant is, by default, unable to meet this standard.

While outside the scope of this project, to address all potential avenues for the applicant, DCOPN additionally finds that the applicant would not meet the threshold necessary to add a new cardiac catheterization lab to the planning district. As illustrated in **Table 6** above, utilization of the cardiac catheterization services at Maryview have remained relatively consistent, with utilization increasing only approximately 30 DEPs between 2018 and 2020. This puts the applicant well below the necessary threshold, barely exceeding half the necessary DEPs per lab required to establish a need to expand. As such, DCOPN concludes that Maryview does not meet this standard.

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.

The applicant meets this standard. Even predicting that utilization will remain consistent, as the objective data presented by VHI shows, the 2020 cardiac catheterization DEPs for Maryview would equate to approximately 429.3 DEPs per lab for the two existing labs and the proposed lab. As there is no evidence that the utilization of the cardiac catheterization labs at Maryview would decrease, DCOPN concludes that the applicant meets this threshold.

[3] 12VAC5-230-80

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. Maryview 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.

Open heart surgical services are available at Maryview and would be performed in the same hybrid operating room in which the requested cardiac catheterization lab would be placed.

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;

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

B. 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. Maryview is not proposing to perform pediatric cardiac catheterization procedures.

C. 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.

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

D. 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. Maryview is not proposing to perform pediatric cardiac catheterization procedures.

Required Considerations Continued

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

While the applicant currently offers cardiac catheterization services, the creation of the hybrid operating room would represent a new type of cardiac surgical service provided at this location. As such, the proposed project would foster some degree of institutional competition. It is unclear, based on the information provided by the applicant, whether this institutional competition would be beneficial. This is of particularly concern as the Commissioner has historically recognized a correlation between a certain volume of procedures and better outcomes

with open heart surgical procedures[4]. Despite this, as no existing providers have opposed the proposed project or voiced concern regarding cardiac surgical volumes, DCOPN is forced to conclude that, at least, the competition generated by approval of the proposed project would not be detrimental to existing providers.

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

As discussed above, DCOPN notes that an existing provider located under five miles from Maryview operates a hybrid operating room performing cardiac procedures. Given the proximity to the applicant, it seems reasonable to assume that the proposed project would have some degree of detrimental effect on the utilization of the operating room at that location. However, as this provider made no objection when other open heart projects in the planning district have received significant opposition, DCOPN is forced to assume that the existing provider located in close proximity to Maryview does not anticipate the proposed project materially affecting their utilization. As such, DCOPN concludes that the proposed project will not materially affect the utilization of other providers in the planning district.

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

The Pro Forma Income Statement (**Table 9**) provided by the applicant projects a net profit of $11,870,799 by the end of the first year of operation and a net profit of $12,218,478 by the end of year two for the proposed project. The applicant asserts that the projected capital costs of the proposed project total $5,000 (**Table 2**), which would be funded using the applicant's accumulated reserves. Accordingly, there are no financing costs associated with this project. As discussed above, DCOPN concluded that the true costs of the project are not quantifiable with the information provided by the applicant. Absent a full accounting of the costs of the project, DCOPN cannot conclude if the proposed project is financially feasible.

With regard to staffing, the applicant asserts that no additional staffing will be required for the proposed project. As such, DCOPN finds that the proposed project is feasible with regards to staffing and concludes that the lack of recruitment would, by its very nature, not adversely affect the staffing of existing providers.

Table 9. Pro Forma Income Statement

	Year 1	Year 2
Gross Revenue	$77,811,301	$80,145,640
Deductions from Revenue	$58,824,098	$60,588,822
Net Patient Services Revenue	$18,987,203	$19,556,818
Total Operating Expenses	$7,116,404	$7,338,340
Excess Revenue Over Expenses	$11,870,799	$12,218,478

Source: COPN Request No. VA-8620

[4] COPN Request Nos. VA-8300, 8306, 8427, & 8436.

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

While the proposed project would introduce new technology to Maryview, and the applicant asserts that it would introduce it to the area, as discussed throughout this report, a hybrid operating room for cardiac surgical procedures exists relatively close to the applicant. As such, DCOPN concludes that the proposed project would not introduce new technology that would promote quality or cost effectiveness in the delivery of inpatient acute care. The proposed project would not increase the potential for provision of services on an outpatient basis nor would it provide any cooperative efforts to meet regional health care needs. DCOPN did not identify any other factors to bring to the Commissioners attention that are not discussed elsewhere in this report.

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

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 Maryview Hospital LLC's request to add a third cardiac catheterization lab at Bon Secours Maryview Medical Center through the relocation of one cardiac catheterization lab from Bon Secours DePaul Medical Center is not consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. As discussed in detail above, DCOPN found that the COPN authorized cardiac catheterization lab that the applicant was seeking to move no longer exists. Prior correspondence from the applicant established that they understood and agreed with this "12-month rule." Additionally, the applicant failed to meet the necessary thresholds to establish a need to expand its cardiac catheterization service.

Moreover, the status quo of two cardiac catheterization labs, however Maryview wishes to employ them, is a preferable alternative to the proposed project. Objective data provided by VHI shows that cardiac catheterization growth at Maryview is flat and remains slightly above 50% of the threshold necessary to justify expansion of services. Additionally, another facility that performs the proposed advanced hybrid operating room cardiac procedures is located a mere 4.1 miles from the applicant. Even should the applicant choose to proceed with the relocation proposed in the equipment registration, ample capacity exists at Maryview provided the applicant does not cease to

operate the relocated cardiac catheterization lab for non-cardiac surgery procedures. Finally, the addition of another cardiac catheterization lab at Maryview would exacerbate the surplus of cardiac catheterization labs within the planning district.

Finally, DCOPN finds that the total capital costs of $5,000 (**Table 2**) neglects to include the majority of the costs associated with the proposed project. While the applicant seeks to utilize a prior equipment registration to defer these costs, the abandonment of the associated plan in favor of the proposed project necessitates that the applicant account for the costs accrued as part of this project. As the majority of the capital costs are not accounted for, DCOPN concludes that the costs are unreasonable.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **denial** of Maryview Hospital LLC's request to add a third cardiac catheterization lab at Bon Secours Maryview Medical Center through the relocation of one cardiac catheterization lab from Bon Secours DePaul Medical Center for the following reasons:

1. The proposed project is not consistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.

2. The COPN authorized cardiac catheterization lab that the applicant seeks to relocate does not exist.

3. There is a surplus of four cardiac catheterization labs in PD 20.

4. The applicant has not established a need for a third cardiac catheterization lab.

5. The status quo of two cardiac catheterization labs, however Maryview wishes to employ them, is a preferable alternative to the proposed project.

6. The costs for the project provided by the applicant do not account for the majority of the capital costs associated with the proposed project.

7. The costs for the proposed project are unreasonable.