VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

May 19, 2020

COPN Request No. VA-8488
Bon Secours Memorial Regional Medical Center
Mechanicsville, Virginia
Addition of cardiac catheterization equipment

Applicant

Bon Secours Memorial Regional Medical Center, Inc. is a Virginia not-for-profit, stock corporation. Effective January 1, 2020, Bon Secours Memorial Regional Medical Center, Inc. was converted to Bon Secours Memorial Regional Medical Center, LLC (BSMR), a nonprofit limited liability company. BSMR is a wholly owned subsidiary of Bon Secours Richmond Health System, Inc., which is a Virginia nonstock, nonprofit corporation. BSMR is located in Planning District (PD) 15, Health Planning Region (HPR) IV.

Background

BSMR operates a 249-bed community hospital in Mechanicsville, Virginia. BSMR provides a full range of services, including, but not limited to, open heart surgery, obstetrics, neonatal special care, and intensive care and step-down intensive care units. In 1995 COPN No.VA-03142 was issued authorizing the replacement and relocation of Richmond Memorial Hospital as BSMR, with all the authorized services present at Richmond Memorial Hospital. Richmond Memorial Hospital had been providing cardiac catheterization services since 1983, pursuant to COPN No. VA-01170 and had been providing open heart surgery since 1988, pursuant to COPN No. VA-02080.

According to the 2018 Virginia Health Information (VHI) data, the most recent year for which such data is available, and DCOPN records, there are 25 stationary cardiac catheterization laboratories in PD 15 (**Table 1**). As shown in **Table 2**, utilization of cardiac catheterization laboratories in PD 15 has been increasing over the past five years with the PD average in 2014 being 66.3% of the State Medical Facilities Plan (SMFP) standard, increasing to 77.4% in 2018.

Table 1. Cardiac Catheterization Laboratory Inventory and Utilization by Facility in PD 15

Facility	Cardiac Catheterization Labs	Total DEPs[1]	Utilization[2]
Bon Secours Memorial Regional Medical Center	3	3,502	97.3%
Bon Secours St. Francis Medical Center	2	1,074	44.8%
Bon Secours St. Mary's Hospital	4	2,621	54.6%
Chippenham Hospital	6	6,567	91.2%
Henrico Doctor's Hospital - Retreat	1	0	0%
Henrico Doctors' Hospital - Forest	5	4,733	78.9%
VCU Health System	4	4,730	98.5%
Total	**25**	**23,227**	**77.4%**

Source: VHI (2018) & DCOPN (interpolations)

Table 2. Cardiac Catheterization Utilization in PD 15, 2013-2017

Diagnostic Equivalent Procedures						
Year	**Cath Labs**	**Diagnostic**	**Therapeutic**	**Same Session**	**Total DEPs**	**Utilization**
2014	24	7,940	1,690	2,595	19,105	66.3%
2015	24	7,825	1,733	2,587	19,052	66.2%
2016	25	8,046	1,975	2,578	19,730	65.8%
2017	25	9,176	2,111	2,773	21,717	72.4%
2018	25	9,609	2,309	3,000	23,227	77.4%

Source: VHI (2014-2018) & DCOPN (interpolations)

As shown in **Table 3**, in the five-year period ending in 2018, total Cardiac Catheterization diagnostic equivalent procedures (DEPs) at BSMR increased by 10%, with an increase of 17% when the increase in non-cardiac catheterization procedures performed in the catheterization laboratory is also considered.

Table 3. Adult Cardiac Catheterization Utilization (in DEPs) at BSMR, 2013-2017

	2014	**2015**	**2016**	**2017**	**2018**	**% Change**
Diagnostic	1072	951	971	1035	1,027	-4%
Therapeutic	98	107	102	120	114	16%
Same Session	643	581	601	683	749	16%
Total Cardiac Cath DEPs	**3,197**	**2,908**	**2,978**	**3,324**	**3,502**	**10%**
Utilization /Lab	89%	81%	83%	92%	97%	
Non Cardiac Cath Procedures[3]	957	1122	1214	1333	1360	42%
Total	**4,154**	**4,030**	**4,192**	**4,657**	**4,862**	**17%**

Source: VHI (2014-2018) & DCOPN (interpolations)

[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] Utilization rate based on SMFP expansion standard of 1,200 cardiac catheterization Diagnostic Equivalent Procedure (DEP) per laboratory detailed in 12 VAC 5-230-400 below.
[3] Non-Cardiac Cath procedures have not been converted to DEPs

Proposed Project

BSMR is requesting authorization to expand its cardiac catheterization service through the acquisition of certain cardiac fluoroscopic guidance software for an existing C-arm located in a hybrid operating room (hybrid OR). The creation of the hybrid OR and the installation of the C-arm are commencing separately from the proposed project and will be completed regardless of the outcome of this request. BSMR asserts that, should the proposed project be approved, the requested cardiac catheterization lab will not be used to perform traditional cardiac catheterization procedures that would typically be performed in a cardiac catheterization laboratory. Instead, the proposed cardiac catheterization lab would be used in the performance of cardiovascular and related procedures as well as transcatheter aortic valve replacement (TAVR) procedures within the hybrid OR. The total capital cost of this proposed project is $94,300 (**Table 4**) and would be funded entirely through the accumulated reserves of BSMR.

Table 4. Capital and Financing Costs

Equipment	$94,300
TOTAL Capital and Financing Costs	**$94,300**

Source: COPN Request 8488

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 of care.**

   As noted above, the proposed cardiac catheterization lab would be used to perform cardiovascular and related procedures as well as TAVR procedures within a hybrid OR. As BSMR is the only open heart program in PD 15 that does not currently offer TAVR, approval of the project would marginally increase access to TAVR to residents of PD 15. The applicant asserts, and DOCPN agrees, that TAVR is rapidly becoming the standard of care for cardiac surgery programs. The applicant cites projections by Sg2, a healthcare consulting firm, showing that the number of TAVR will surpass traditional valve surgical procedures by 2022. DCOPN, in a recent open heart surgery report, adopted supplemental data supporting the assertion that TAVRs are the fastest growing cardiac procedure[4] and concurs with BSMR’s assertion here

[4] COPN Request No. VA-8436

regarding the growth of TAVR in PD 15. As such, DCOPN concludes that approval of the proposed project would increase access to a procedure that is rapidly becoming a standard of care in cardiac surgery programs.

Geographically, BSMR is located approximately 0.5 miles from I-295 at the intersection of Meadowbridge Road and Atlee Road. I-295 connects to both I-95 and I-64, which serve as major transportation routes throughout the state. The applicant asserts that BSMR's campus is not accessible by public transportation.

Population also plays a major role in determining the need for certain medical services in a planning district. **Table 5** shows projected population growth in PD 15 through 2030.

Table 5. Population Projections for PD 15, 2010-2030

Locality	2010	2020	% Change 2010-2020	Avg Ann % Chg	2030	% Change 2020-2030	Avg Ann % Chg 2020-2030
Charles City	7,256	6,982	-3.78%	-0.38%	6,941	-0.59%	-0.06%
Chesterfield	316,236	353,841	11.89%	1.10%	396,647	12.10%	1.15%
Goochland	21,717	23,547	8.43%	0.79%	26,702	13.40%	1.27%
Hanover	99,863	109,244	9.39%	0.88%	119,360	9.26%	0.89%
Henrico	306,935	332,103	8.20%	0.77%	363,259	9.38%	0.90%
New Kent	18,429	23,474	27.37%	2.39%	28,104	19.72%	1.82%
Powhatan	28,046	29,909	6.64%	0.63%	33,440	11.80%	1.12%
Richmond city	204,214	232,533	13.87%	1.28%	245,483	5.57%	0.54%
Total PD 15	**1,002,696**	**1,111,633**	**10.86%**	**1.01%**	**1,219,936**	**9.74%**	**0.93%**
PD 15 65+	116,609	172,249	47.72%	3.98%	224,417	30.29%	2.68%
Virginia	8,001,024	8,655,021	8.17%	0.77%	9,331,666	7.82%	0.76%
Virginia 65+	976,937	172,249	38.44%	3.22%	1,723,382	27.43%	2.45%

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

As depicted in **Table 5**, Weldon-Cooper projects that the total population of PD 15 will increase by approximately 11% from 2010 to 2020, and by approximately 10% from 2020 to 2030. Overall, the planning district is projected to add an estimated 108,937 people in the 10-year period ending in 2020—an increase of approximately 10,894 people annually. Regarding the 65+ age group for PD 15, Weldon-Cooper projects a more rapid increase in population growth (an approximate 48% increase from 2010 to 2020 and approximately 30% from 2020 to 2030). This is significant, as this population group typically uses health care resources, including cardiac services, at a rate much higher than those individuals under the age of 65 do. When compared to statewide population projections for the same period, it is evident that the population of PD 15 is increasing at a much faster rate than Virginia as a whole. Weldon-Cooper projects that statewide, the total population will increase by approximately 8% from 2010 to 2020, and by another approximately 8% from 2020 to 2030. Weldon-Cooper further projects that statewide, the 65+ age cohort population will increase at a rate of approximately 38% from 2010 to 2020, and approximately 27% from 2020 to 2030.

Most of the population increase in PD 15 is attributed to Chesterfield County, Henrico County, and Richmond. With a projected population of 109,244 in 2020, up from 99,863 in 2010, Hanover County, where the proposed project would be located, has the fourth largest population base in the Planning District. It is projected that by 2020, nearly 10% of the population of PD 15 will live in Hanover County, which is projected to grow at a rate of 0.88% annually.

DCOPN did not identify any other unique geographic, socioeconomic, cultural, transportation, or other barriers to care in the planning district.

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 23 letters of support for the proposed project from local physicians. Collectively, these letters discussed the growth of TAVR, its associated benefits, and how it has become the standard of care for facilities offering cardiovascular surgery. Additionally, these letters stated that approval of the proposed project would allow BSMR to stay current and prepare for future growth. DCOPN did not receive any letters of opposition to the proposed project.

Public Hearing

DCOPN conducted the required public hearing on May 5, 2020. A total of 9 individuals were in attendance. The project was presented by three individuals representing BSMR. Two members of the public, both doctors associated with BSMR, spoke in support of the proposed project. No members of the public spoke in opposition of the proposed project.

(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 proposed project is more advantageous than the alternative of the status quo. As previously discussed, TAVR is rapidly becoming the standard of care for cardiac surgery programs, and is expected to surpass traditional valve replacement procedures in the next several years. Additionally, as noted in **Table 5** above, the population of PD 15 that are 65 years of age or older is increasing significantly. As residents of the planning district over the age of 64 require cardiac services more frequently than younger residents, DCOPN concludes that demand for cardiac services will only continue to grow as the percentage of the population over the age of 64 increases. Under the status quo, DCOPN anticipates that the significant growth of TAVR will likely lead to the current programs that offer the treatment becoming overburdened as the portion of the population of PD 15 that is age 65 or older increases. Approval of the project would allow for providers to continue to meet the growing demands for TAVR within PD 15. As such, DCOPN concludes that the proposed project is more advantageous than the status quo.

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

Currently there is no organization in HPR IV designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 15. Therefore, this consideration is not applicable to the review of the proposed project.

(iv) Any costs and benefits of the project;

As demonstrated in **Table 2** above, the total capital cost of the proposed project is $94,300 and would be funded through BSMR's accumulated reserves. This price is substantially lower than other projects to add one cardiac catheterization lab to an existing operating room. For example, COPN No. VA-04603 issued to Riverside Hospital, Inc. d/b/a Riverside Regional Medical Center to add cardiac catheterization equipment in a GPOR, which cost approximately $3,335,953. This is because the sole cost associated with the proposed project is for the acquisition of certain cardiac fluoroscopic guidance software for an existing C-arm, whereas the other projects proposed to purchase the cardiac catheterization machinery as part of the project. As discussed extensively throughout this report, the proposed project offers several benefits. For example, it would increase access to TAVR within PD 15. Additionally, because BSMR is the only cardiac surgery program in the planning district to not offer TAVR, it would increase institutional competition by enabling BSMR to provide a procedure that is rapidly becoming the standard of care in cardiac surgery programs. Finally, as discussed above, approval of the project would allow for providers to continue to meet an aging population's growing demands for TAVR within PD 15.

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

The Pro Forma Income Statement (**Table 6**) provided by the applicant proposes the provision of 2.8% charity care based on gross patient services revenue. According to regional and statewide data regularly collected by VHI, for 2018, the most recent year for which such data is available, the average amount of charity care provided by HPR IV facilities was 3.7% of all reported total gross patient revenues (**Table 7**). In that same year, BSMR provided 4.42% of its gross patient revenue in the form of charity care. Should the Commissioner approve the request, BSMR is expected to provide a level of charity care for total gross patient revenues that is no less than the equivalent average for charity care contributions in HPR IV.

Table 6. BSMR's Pro Forma Income Statement

	Year 1	Year 2
Gross Patient Revenue	15,511,272	$34,768,627
Revenue Deductions	($10,951,425)	($24,570,363)
Charity Care	($426,679)	($957,287)
Net Patient Revenue	**$4,133,168**	**$9,240,977**
Expenses		
Salaries, Wages and Benefits	$1,417,363	$3,212,132
Supplies	$1,167,996	$2,667,739
Purcahsed Services	$52,561	$116,684
Rent, Utility, and Other	$20,666	$46,205
Depreciation and Interest	$984,206	$984,206
Total Operating Expenses	**$3,642,792**	**$7,026,966**
Net Income	**$490,376**	**$2,214,011**

Source: COPN Request No. VA-8488

Table 7. HPR IV 2018 Charity Care Contribution

Health Planning Region IV			
2018 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	**Gross Patient Revenues**	**Adjusted Charity Care Contribution**	**Percent of Gross Patient Revenue:**
Bon Secours Richmond Community Hospital	$674,969,731	$42,666,943	6.32%
VCU Health System	$5,621,665,960	$352,825,510	6.28%
Southside Community Hospital	$293,702,705	$14,237,351	4.85%
Bon Secours St. Francis Medical Center	$970,223,902	$43,084,096	4.44%
Bon Secours Memorial Regional Medical Center	$1,552,613,092	$68,611,063	4.42%
Bon Secours St. Mary's Hospital	$2,176,359,866	$77,859,815	3.58%
Sentara Halifax Regional Hospital	$294,576,590	$9,953,244	3.38%
Southside Regional Medical Center	$1,956,522,794	$63,281,154	3.23%
VCU Community Memorial Hospital	$260,605,004	$7,269,351	2.79%
CJW Medical Center	$6,586,796,429	$176,068,998	2.67%
Henrico Doctors' Hospital	$4,501,141,313	$97,784,217	2.17%
Southern Virginia Regional Medical Center	$208,002,057	$4,386,121	2.11%
John Randolph Medical Center	$839,825,455	$17,429,142	2.08%
Vibra Hospital of Richmond LLC	$120,847,463	$0	0.00%
Cumberland Hospital for Children and Adolescents	$60,602,814	$0	0.00%
Total $ & Mean %	**$26,118,455,175**	**$975,457,005**	**3.7%**

Source: VHI (2018)

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

The State Medical Facilities Plan (SMFP) contains standards and criteria for institutional expansion and the addition or expansion of cardiac catheterization services. They are as follows:

Part I. 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 8** below, the utilization of BSMR's three cardiac catheterization labs has steadily increased since 2015. BSMR asserts in their application that, in January through October 2019, their three cardiac catheterization labs performed 3,658 DEPs. While DCOPN's calculations using the number of visits places the number of DEPs at 3,654, this lower number still exceeded the 1,200 procedure utilization threshold. While DCOPN does not have VHI data for 2019 to confirm this, given the continued growth of cardiac catheterization at BSMR, DCOPN finds it extremely likely that BSMR's utilization in 2019 exceeded the 1,200 procedure threshold, and concludes that the applicant has established an institutional need. However, the applicant stated, and DCOPN agrees, that the proposed project would not address the institutional need at BSMR because it would not be performing traditional cardiac catheterization procedures. As such, DCOPN concludes that, while BSMR has established an institutional need for an additional cardiac catheterization lab, the proposed project will not address the BSMR's need having exceeded its current service capacity to provide such service.

Table 8. BSMR Utilization 2014-2018

Diagnostic Equivalent Procedures						
Year	**Cath Labs**	**Diagnostic**	**Therapeutic**	**Same Session**	**Total DEPs**	**Utilization**
2014	1,072	98	643	3,197	1,065.7	88.81%
2015	951	107	581	2,908	969.3	80.78%
2016	971	102	601	2,978	992.7	82.72%
2017	1,035	120	683	3,324	1,108.0	92.33%
2018	1,027	114	749	3,502	1,167.3	97.28%

Source: VHI Data (2014-2018)

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 detailed in Table 1 above, in addition to BSMR, Bon Secours Richmond Health System operates two other locations in PD 15, Bon Secours St. Francis Medical Center (St. Francis) and Bon Secours St. Mary's Hospital (St. Mary). In 2018, the last year for which DCOPN has data from VHI, both facilities had underutilized cardiac catheterization labs that could be reallocated to BSMR without creating an institutional need at that facility. Using the 2018 data provided by VHI, reallocating one of the two cardiac catheterization labs at St. Francis would leave the remaining lab with a utilization of 89.6% of the SMFP threshold and reallocating one of the four cardiac catheterization labs at St. Mary would leave the three remaining labs with a utilization of 72.8% of the SMFP threshold. However, looking at the growth of utilization at both facilities, DCOPN conclude that reallocation of cardiac catheterization labs at either facility would likely create an institutional need at that location within one to two years. As such, DCOPN concludes that there are not cardiac catheterization labs at other facilities within the Bon Secours Richmond Health System that could be reallocated to BSMR without creating a deficit at that location.

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 15.

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 **Figures 1 and 2** identifies the boundaries of PD 15. 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 15. In **Figure 2,** the grey shading illustrates the area that is within 60 minutes driving time one way under normal driving conditions of all TAVR service providers in PD 15. Based on the shaded areas in **Figures 1 and 2**, it is reasonable to conclude that all of the population of PD 15 are currently within 60 minutes driving time one way under normal traffic conditions of cardiac catheterization and TAVR services.

Figure 1

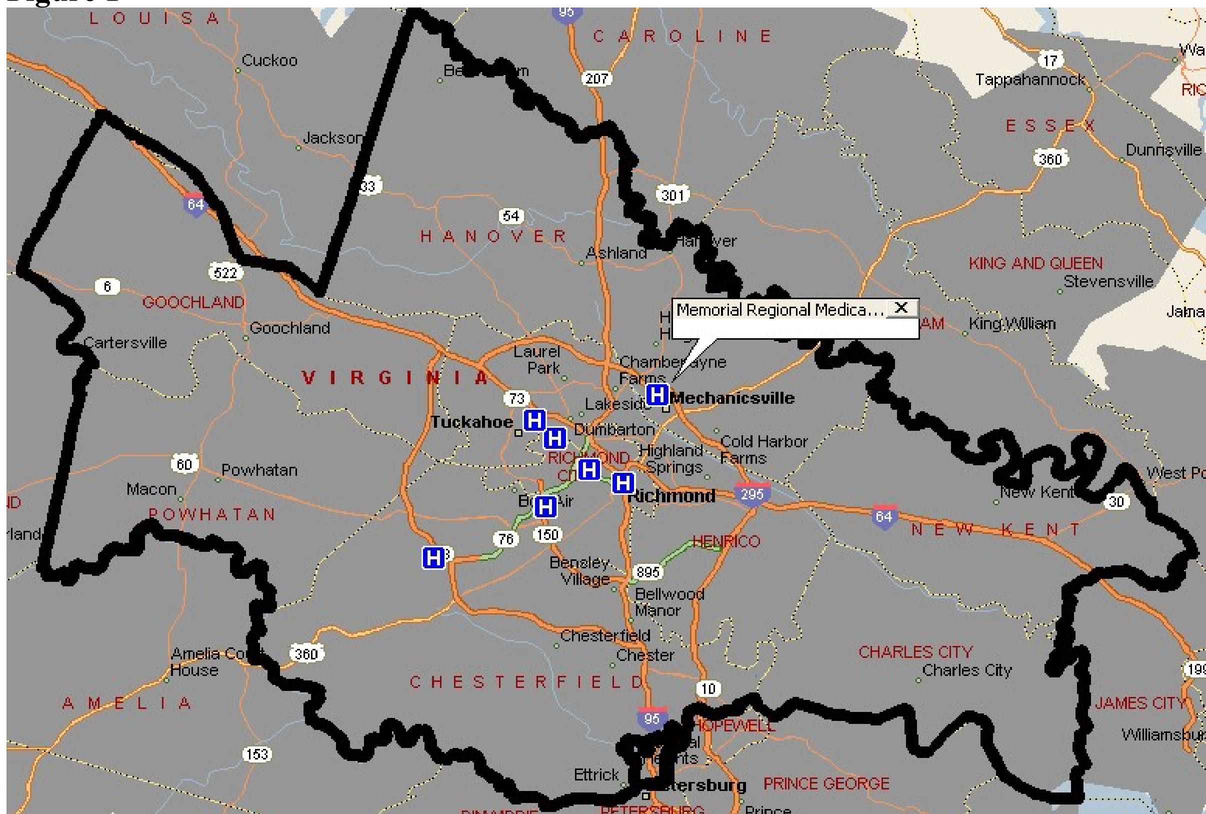
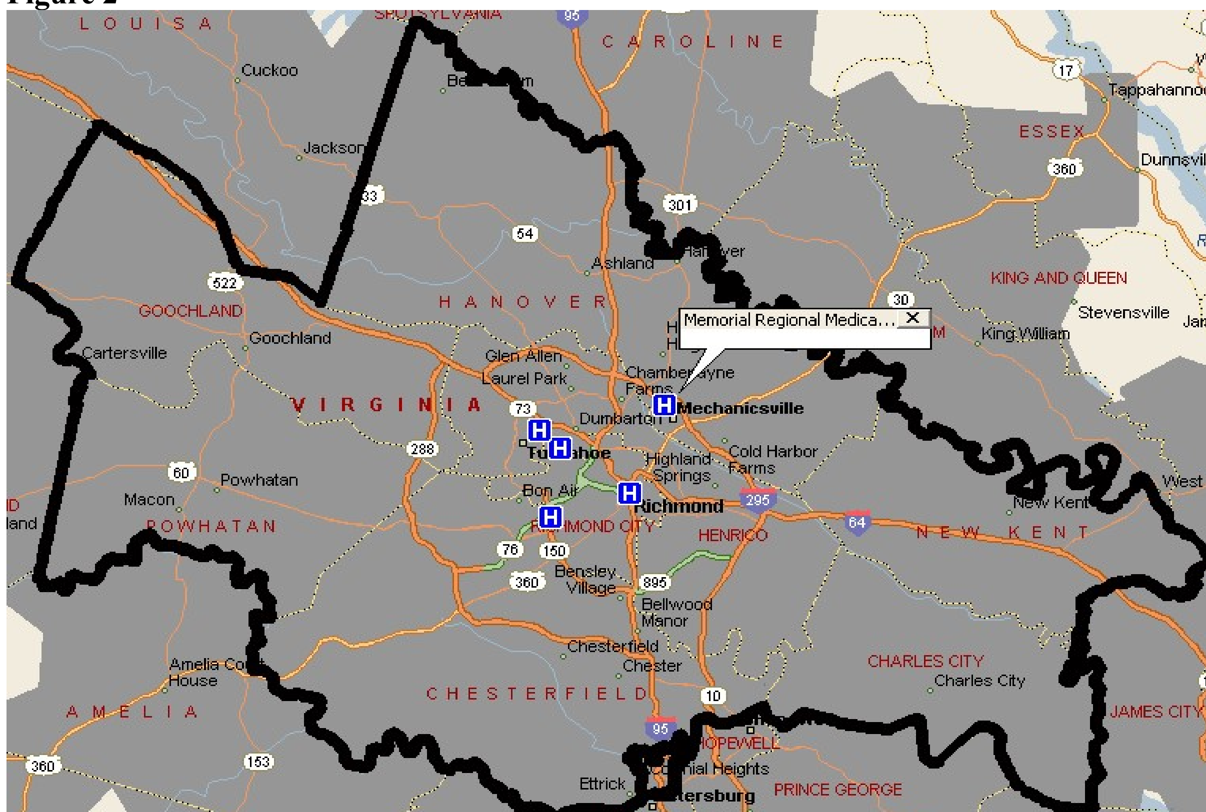


Figure 2



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.**

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.

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 would 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

As illustrated in **Table 3** above, utilization of the cardiac catheterization services at BSMR have increased by 10% with regard to total DEPs between 2014 and 2018. As discussed in 12VAC5-230-80 above, while BSMR has not reached the 1,200 DEPs per existing lab, their utilization has steadily increased since 2015, and DCOPN concludes that, while it does not possess 2019 data, the assertions made by the applicant regarding cardiac catheterization utilization are consistent with the increases in utilization seen between 2015 and 2018. Moreover, as discussed above and noted in **Table 5**, the population of PD 15 that are 65 years or older is increasing significantly. As residents of the planning district over the age of 64 require cardiac catheterization procedures more frequently than younger residents, DCOPN concludes that it is reasonable to assume that BSMR's growth in utilization will continue moving forward. As such, DCOPN concludes that BSMR meets 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.

BSMR asserts that this section is not applicable to the proposed project as the proposed cardiac catheterization lab will not perform traditional cardiac catheterization procedures but rather be placed in a hybrid operating room to perform cardiovascular procedures and TAVR. BSMR anticipates that they will perform 95 procedures in the first year and 108 in the second year.

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. BSMR is not proposing to provide pediatric cardiac catheterization procedures.

12 VAC 5-230-420. Non-emergent Cardiac Catheterization.
Proposals to provide elective interventional cardiac procedures such as PTCA, transseptal puncture, transthoracic left ventricle puncture, myocardial biopsy or any valvuloplasty procedures, diagnostic pericardiocentesis or therapeutic procedures should be approved only when open heart surgery services are available on-site in the same hospital in which the proposed non-emergent cardiac service will be located.

Open heart surgical services are available at BSMR and will 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;

BSMR 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. BSMR is not proposing to provide 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.

BSMR provided assurances that cardiac catheterization services are under the direct supervision of physicians 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. BSMR is not proposing to provide 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.

As discussed above, as BSMR is the sole open heart surgery program that does not offer TAVR, approval of the proposed project will only marginally improve access. Moreover, given that four health systems within PD 15, including Bon Secours Health System, already offer TAVR, DCOPN concludes that approval of this project will not materially 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.

BSMR is part of the Bon Secours Richmond Health System and is an established provider of both cardiac catheterization and open heart services in PD 15. As discussed above, DCOPN concludes, based on data provided with the application and historic trends in cardiac catheterization use at BSMR, that BSMR's cardiac catheterization laboratories operated in excess of the 1,200 DEPs utilization threshold in 2019. Moreover, DCOPN concluded that, while underutilized cardiac catheterization labs existed at two facilities within the Bon Secours Richmond Health System, the historic growth at both locations were sufficient to determine that reallocation of a cardiac catheterization lab from either location would create a deficit at that location within the next one to two years. The proposed project, however, will not alleviate the burden on BSMR's cardiac catheterization labs. As discussed above, the proposed project would not be used as a traditional cardiac catheterization lab, but instead would be used in the performance of cardiovascular and related procedures as well as TAVR procedures within a hybrid OR. As such, DCOPN concludes that the proposed project will not materially affect the utilization or efficiency of existing services or facilities.

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

As previously discussed, the cost of the proposed project is far less than other projects to place cardiac catheterization equipment in an existing operating room and will be funded through BSMR's accumulated reserves. As such, DCOPN concludes that the proposed project is financially feasible. With regard to staffing, the proposed project only requires one full time radiologic technician. The applicant provided a detailed series of methods by which they intend to identify and hire the required radiologic technician. Given the modest scope of the necessary staffing and the scope of the methods employed by Bon Secours Health System to identify and hire the staff, DCOPN concludes that the proposed project is feasible with regard to staffing.

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 proposed project does not seek to introduce new technology to the planning district, but would introduce new technology that promotes quality and cost effectiveness in the delivery of health care services at BSMR by the introduction of TAVR. As discussed extensively throughout this report, TAVR is rapidly becoming the standard of care. Additionally, the benefits of TAVR include decreased recovery time with lessened instances of morbidity for patients. As such, DCOPN concludes that the proposed project would provide improvements in the delivery of health services through the introduction of TAVR to BSMR.

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 the citizens of the Commonwealth, including indigent or underserved populations.

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

DCOPN Staff Findings and Conclusions

DCOPN finds that the proposed project to expand BSMR's cardiac catheterization services through the acquisition of certain cardiac fluoroscopic guidance software for an existing C-arm located in a hybrid operating room CT is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia.

Furthermore, DCOPN finds that the proposed project is more advantageous than the status quo. As discussed above, the percentage of the population that are 65 years or older is increasing in PD 15. As patients over the age of 64 require cardiac services more frequently than younger patients, the demand for cardiac services are will increase alongside the aging population of PD 15. As the proposed cardiac catheterization lab will be used solely to perform TAVR, a procedure that is rapidly becoming the standard of care, and cardiovascular and related procedures within a hybrid OR, the proposed project will help to address the growing need in the population for cardiac services.

No letters of opposition to the proposed project were submitted and no opposition was expressed at the public hearing. Finally, DCOPN finds that the total capital costs of the proposed project are $94,300 and, which would be funded using BSMR's accumulated reserves, are reasonable and inexpensive compared to previously approved projects to add a cardiac catheterization lab to an existing operating room. For example, COPN No. VA-04603 issued to Riverside Hospital, Inc. d/b/a Riverside Regional Medical Center to add cardiac catheterization equipment in a GPOR, which cost approximately $3,335,953.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **conditional approval** of Bon Secours Memorial Regional Medical Center, LLC's COPN Request No. VA-8488 to expand their cardiac catheterization services through the acquisition of certain cardiac fluoroscopic guidance software for an existing C-arm located in a hybrid operating room. DCOPN's recommendation is based on the following findings:

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

2. The proposed cardiac catheterization lab will be used solely to perform TAVR and cardiovascular and related procedures within a hybrid OR.

3. The project is more favorable than the status quo.

4. DCOPN has not received any letters of opposition to the proposed project and no opposition was expressed at the public hearing.

5. There are capital costs for the proposed project reasonable and inexpensive compared to projects of this type.

DCOPN's recommendation is contingent upon BSMR's agreement to the following indigent care condition:

Bon Secours Memorial Regional Medical Center, LLC will provide surgical services to all persons in need of this service, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and facilitate the development and operation of primary care services to medically underserved persons in an aggregate amount

equal to at least 3.7% of Bon Secours Memorial Regional Medical Center, LLC's total patient services revenue derived from cardiac catheterization services provided at Bon Secours Memorial Regional Medical Center as 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. 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. Bon Secours Memorial Regional Medical Center, LLC will accept a revised percentage based on the regional average after such time regional charity care data valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. is available from Virginia Health Information. The value of charity care provided to 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.