

COMMONWEALTH of VIRGINIA

M. Norman Oliver, MD, MA State Health Commissioner Department of Health
PO BOX 2448
RICHMOND. VA 23218

TTY 7-1-1 OR 1-800-828-1120

January 10, 2022

Mr. Thomas J. Stallings McGuire Woods LLP Gateway Plaza 800 East Canal Street Richmond, Virginia 23219

RE: COPN No. VA-04767

Spotsylvania Medical Center, Inc., Fredericksburg, Virginia Addition of One Cardiac Catheterization Lab at Spotsylvania Regional Medical Center

Dear Mr. Stallings:

In accordance with Chapter 4, Article 1.1 of Title 32.1 of the Code of Virginia of 1950 (the Code), as amended, I reviewed the application and all supporting documents submitted by Spotsylvania Medical Center, Inc. to add one cardiac catheterization lab at Spotsylvania Regional Medical Center.

As required by Section 32.1-102.3B of the Code, I have considered all factors that must be taken into account in a determination of public need, and I have concluded that **conditional approval** of the request is warranted based on the following findings:

- 1. The project is generally 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 capital costs are reasonable.
- 3. The proposed project appears economically viable both in the immediate and in the long-term.
- 4. No reasonable alternatives to the proposed project exist.
- 5. The applicant has adequately demonstrated a unique institutional need for the additional cardiac catheterization lab.
- 6. There is no known opposition to the proposed project.



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Mr. Thomas J. Stallings COPN VA-04767 January 10, 2022 Page 2

7. Approval of the proposed project is not likely to have a significant negative impact on the staffing or utilization of existing PD 16 providers of cardiac catheterization services.

This certificate is valid for the period January 10, 2022 through January 9, 2023. The total authorized capital cost of the project is \$99,556.

Please file two copies of the application for a certificate extension with the Department no later than 30 days before the expiration date of the certificate. Part VIII of the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations identifies the filing requirements and review procedure for certificate extension requests.

Sincerely,

M. Norman Oliver, MD, MA State Health Commissioner

Enclosures

cc: Allyson Tysinger, Senior Assistant Attorney General, Commonwealth of Virginia Erik Bodin, Director, Division of Certificate of Public Need Deborah K. Waite, Operations Manager, Virginia Health Information Olugbenga Obasango, MD, MPH, District Director, Rappahannock Health District

MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED COMMONWEALTH OF VIRGINIA DEPARTMENT OF HEALTH

THIS CERTIFIES THAT Spotsylvania Regional Medical Center, Inc. is authorized to initiate the proposal as described below.

NAME OF FACILITY: Spotsylvania Regional Medical Center

LOCATION: 4600 Spotsylvania Parkway, Spotsylvania, Virginia 22408

OWNERSHIP AND CONTROL: Spotsylvania Regional Medical Center, Inc.

SCOPE OF PROJECT: Add one cardiac catheterization lab, resulting in a total complement of two cardiac catheterization labs. Capital costs associated with this project total \$99,556. The project is expected to be completed by October 20, 2022. This certificate is issued with the condition that appears on its reverse.



Pursuant to Chapter 4, Article 1:1 of Title 32.1, Sections 32.1-102.1 through 32.1-102.12 of the Code of Virginia (1950), as amended and the policies and procedures promulgated thereunder, this Medical Care Facilities Certificate of Public Need is issued contingent upon substantial shall be submitted to the State Health Commissioner within twelve (12) months from the date of issuance along with adequate assurance of completion within a reasonable time period. The Commissioner reserves the right not to renew this Certificate in the event the applicant fails and continuing progress towards implementation of the proposal within twelve (12) months from the date of issuance. A progress report to fulfill these conditions. This Certificate is non-transferable and is limited to the location, ownership, control and scope of the project shown

Certificate Number: VA-04767

Date of Issuance: January 10, 2022

Expiration Date: January 9, 2023

M. Norman Oliver, MD, MA, State Health Commissioner

and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. Compliance cardiac catheterization services as valued under the provider reimbursement methodology utilized by the Centers for Medicare amount equal to at least 3.0% of Spotsylvania Regional Medical Center, Inc.'s total patient services revenue derived from services and facilitate the development and operation of primary care services to medically underserved persons in an aggregate regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in appropriately certified financial statements documenting compliance with the preceding requirement. Spotsylvania Regional with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise Spotsylvania Regional Medical Center, Inc. will provide cardiac catheterization services to all persons in need of this service, of the Social Security Act, 42 U.S.C. § 1395 et seq. reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII Information. The value of charity care provided to individuals pursuant to this condition shall be based on the provider reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. is available from Virginia Health valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for Medical Center, Inc. will accept a revised percentage based on the regional average after such time regional charity care data

applicant's service area. development and operation of primary and specialty medical care services in designated medically underserved areas of the 1396 et seq.), and 10 U.S.C. § 1071 ct seq. Additionally, Spotsylvania Regional Medical Center, Inc. will facilitate the 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. § Spotsylvania Regional Medical Center, Inc. will provide cardiac catheterization services to individuals who are eligible for

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need Staff Analysis

November 19, 2021

COPN Request No. VA-8583Spotsylvania Regional Medical Center, Inc.

Spotsylvania, Virginia

Add One Cardiac Catheterization Lab at

Spotsylvania Regional Medical Center

COPN Request No. VA-8584
Mary Washington Hospital, Inc.

Fredericksburg, Virginia

Add One Cardiac Catheterization Lab
at Mary Washington Hospital

Applicant

COPN Request No. VA-8583: Spotsylvania Regional Medical Center, Inc. (SRMC)

Spotsylvania Medical Center, Inc. is a Virginia-domiciled for-profit stock corporation that was organized in November 2005. SRMC is a wholly-owned subsidiary of HCA Health Services of Virginia, Inc., which in turn is an affiliated entity of HCA, Inc. HCA, Inc., which is headquartered in Nashville, Tennessee, is a for-profit, Delaware domiciled holding company. Spotsylvania Medical Center Inc. is the legal name of Spotsylvania Regional Medical Center (SRMC), which is located in Fredericksburg, Virginia in Planning District (PD) 16 within Health Planning Region (HPR) I.

COPN Request No. VA-8584: Mary Washington Hospital, Inc. (MWH)

Mary Washington Hospital, Inc. is owned and operated by Mary Washington Healthcare, a 501(c)(3) Virginia not-for-profit, non-stock corporation located in the city of Fredericksburg, Virginia in PD 16 within HPR I.

Background

Cardiac Catheterization Labs and Utilization in PD 16

According to DCOPN records, presently there are five stationary cardiac catheterization (cardiac cath) laboratories in PD 16 (**Table 1**). According to 2019 Virginia Health Information (VHI) data, the most recent year for which such data is available, the collective PD 16 inventory performed a total of 5,625 DEPs in 2019, and operated at a collective utilization rate of 94%. As shown in **Table 2** below, utilization of cardiac cath laboratories in PD 16 has increased from 74% in 2015 to 94% in 2019.

Table 1. PD 16 Cardiac Catheterization	Laboratories and Utilization: 2019
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Facility	Cardiac Cauterization Labs	Total DEPs ¹	Utilization Rate
Mary Washington Hospital	3	4,026	112%
Spotsylvania Regional Medical Center	1	1,230	103%
Stafford Hospital Center	1	369	31%
TOTAL	5	5,625	94%

Source: VHI (2019) and DCOPN (interpolations)

Table 2. Historical Cardiac Catheterization Utilization in PD 16: 2015-2019

Year	Cath Labs	Diagnostic	Therapeutic	Same Session	TOTAL DEPs	Utilization
2019	5	1,980	426	3,219	5,625	94%
2018	5	1,595	438	2,727	4,760	70%
2017	5	1,831	184	2,829	4,844	81%
2016	5	1,778	160	2,670	4,608	77%
2015	5	1,778	234	2,421	4,433	74%

Source: VHI (2015-2019) and DCOPN (interpolations)

Note: Utilization rate based on SMFP expansion standard of 1,200 cardiac catheterization Diagnostic Equivalent Procedures (DEPs) per laboratory

COPN Request No. VA-8583: Spotsylvania Regional Medical Center, Inc. (SRMC)

As demonstrated above in **Table 1**, in 2019, SRMC's sole existing cardiac cath laboratory performed 1,239 DEPs, operating at 103% of the SMFP threshold for expansion. As demonstrated below in **Table 3**, in the five-year period ending in 2019, total cardiac cath DEPs at SRMC increased by 49.5%.

Table 3. Adult Cardiac Catheterization Utilization (in DEPs) at SRMC: 2015-2019

	2015	2016	2017	2018	2019	% Change
Diagnostic	236	259	200	224	378	60.2%
Therapeutic	116	86	106	92	144	24.1%
Same Session	471	540	426	522	708	50.3%
Total Cardiac Cath DEPs	823	885	732	838	1,239	49.5%
Utilization Rate	69%	74%	61%	70%	103%	49.3%

Source: VHI (2015-2019) and DCOPN Records.

COPN Request No. VA-8584: Mary Washington Hospital, Inc. (MWH)

As demonstrated above in **Table 1**, in 2019, MWH's three existing cardiac cath laboratories performed 4,026 DEPs, operating at 112% of the SMFP threshold for expansion. As demonstrated below in **Table 4**, in the five-year period ending in 2019, total cardiac cath DEPs at MWH increased by 28.5%.

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).

	2015	2016	2017	2018	2019	% Change
Diagnostic	1,252	1,244	1,394	1,190	1,403	12.1%
Therapeutic	102	8	66	270	214	109.8%
Same Session	2,779	2,031	2,277	2,091	2,409	35.4%
Total Cardiac Cath DEPs	3,133	3,283	3,737	3,551	4,026	28.5%
Utilization Rate	87%	91%	104%	99%	112%	28.7%

Source: VHI (2015-2019) and DCOPN Records.

Proposed Projects

COPN Request No. VA-8583: Spotsylvania Regional Medical Center, Inc. (SRMC)

SRMC proposes to expand its cardiac cath laboratory service with the addition of a second cath lab on the hospital campus. The second cath lab will use existing electrophysiology laboratory space and equipment. The equipment will be upgraded and minor renovations will be made to the existing space. The total projected capital cost of the proposed project is \$99,556, the entirety of which will be funded using the accumulated reserves of the applicant (**Table 5**). Accordingly, there are no financing costs associated with the proposed project. If approved, the applicant anticipates construction on the proposed project to begin within six months of Certificate of Public Need (COPN) issuance and to be complete within nine months of COPN issuance. The applicant anticipates an opening date within ten months of COPN issuance. The applicant cites a unique institutional need for the proposed additional cath lab.

Table 5. SRMC Capital Costs

Direct Construction Costs	\$30,052
Equipment Not Included in Construction Contract	\$69,054
TOTAL Capital Costs	\$99,556

Source: COPN Request No. VA-8583

COPN Request No. VA-8584; Mary Washington Hospital, Inc. (MWH)

MWH proposes to expand its existing cardiac cath service through the addition of a fourth cardiac cath lab. The proposed project involves the reconfiguration of space in the existing cardiac cath suite and adjacent shell space at MWH. The proposed cardiac cath lab will be built inside of shell space along the west side of the hospital campus, adjacent to the existing cath and electrophysiology suite and will be approximately 1,000 gross square feet. As proposed, the fit out will support one cath lab, scrub, and equipment spaces. Preparation, recovery and support spaces already exist. The total capital cost of the proposed project is \$3,521,088, the entirety of which will be funded using the accumulated reserves of the applicant (**Table 6**). Accordingly, there are no financing costs associated with this project. If approved, the applicant anticipates construction on the proposed project to begin in June of 2022 and to be complete in December of 2022. The applicant anticipates a January 2023 target date of opening. The applicant cites a unique institutional need for the proposed addition.

Table 6. MWH Capital Costs

Direct Construction Costs	\$1,049,400
Equipment Not Included in Construction Contract	\$2,328,700
Architectural and Engineering Fees	\$142,988
TOTAL Capital Costs	\$3,521,088

Source: COPN Request No. VA-8584

Project Definition

Section 32.1-102.1 of the Code of Virginia defines a project, in part, as "The addition by an existing medical care facility described in subsection A of any new medical equipment for the provision of cardiac catheterization..." A medical care facility includes "any facility licensed as a hospital, as defined in § 32.1-123."

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;

COPN Request No. VA-8583: Spotsylvania Regional Medical Center, Inc. (SRMC) Geographically, SRMC is located in Spotsylvania County, immediately east of Interstate 95 and immediately south of the Spotsylvania Parkway extension. SRMC is proximate to, and easily accessible from, Routes 1, 2, 3, 17, and 301, making the location highly accessible. As a result of its work with Fredericksburg Regional transit, Spotsylvania Regional Medical Center has a bust stop directly on the hospital campus.

As will be discussed in more detail later in this staff analysis report, DCOPN notes that cardiac cath services are well within a 60-minute drive one way under normal conditions of 95% of the population of PD 16. Furthermore, DCOPN notes that the applicant is a current provider of this service. Accordingly, DCOPN contends that approval of the proposed project is not likely to improve geographic access to services in any meaningful way.

Regarding socioeconomic barriers to access to the applicant's services, according to regional and statewide data regularly collected by VHI, for 2019, the most recent year for which such data is available, the average amount of charity care provided by HPR I facilities was 3.0% of all reported total gross patient services revenues (**Table 7**). The Pro Forma Income Statement provided by the applicant (**Table 8**) anticipates a charity care contribution equal to 4.16% of gross revenues derived from cardiac cath services at SRMC, an amount greater than the average HPR I contribution. DCOPN notes that recent changes to §32.1-102.4B of the Code of Virginia now require DCOPN to place a charity care condition on all applicants seeking a COPN. For this reason, DCOPN recommends that the proposed project, if approved, be subject to a 4.16% charity care condition to be derived from total cardiac cath gross patient services revenue.

DCOPN further notes that this condition contains a provision allowing for the reassessment of the charity care rate once more reliable data regarding the full impact of Medicaid expansion in the Commonwealth becomes available.

Table 7. 2019 HPR I Charity Care Contributions

Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue
University of Virginia Medical Center	\$5,908,975,470	\$281,698,729	4.77%
Culpeper Regional Hospital	\$380,434,774	\$13,782,293	3.62%
Sentara RMH Medical Center	\$990,510,384	\$31,826,597	3.21%
Carilion Stonewall Jackson Hospital	\$128,681,326	\$4,054,332	3.15%
Martha Jefferson Hospital	\$738,572,393	\$16,357,090	2.21%
Shenandoah Memorial Hospital	\$138,346,148	\$2,949,504	2.13%
Page Memorial Hospital	\$67,252,269	\$1,411,441	2.10%
Warren Memorial Hospital	\$159,448,610	\$2,896,105	1.82%
Augusta Medical Center	\$1,084,003,117	\$17,664,291	1.63%
Spotsylvania Regional Medical Center	\$593,173,888	\$9,003,897	1.52%
Winchester Medical Center	\$1,547,423,083	\$22,313,262	1.44%
UVA Transitional Care Hospital	\$62,823,527	\$851,414	1.36%
Bath Community Hospital	\$25,106,383	\$268,755	1.07%
Mary Washington Hospital	\$1,504,703,712	\$12,119,248	0.81%
Stafford Hospital Center	\$321,401,662	\$2,151,628	0.67%
Fauquier Hospital	\$448,588,022	\$2,715,780	0.61%
Total Facilities			16
Median			1.7%
Total \$ & Mean %	\$14,099,444,768	\$422,064,366	3.0%

Source: VHI (2019)

Table 8. SRMC Pro Forma Income Statement

	Year 1 (2022)	Year 2 (2023)
Gross Revenue	\$17,736,764	\$19,498,519
Deductions from Revenue	\$6,961,241	\$7,768,821
Net Revenue	\$10,775,523	\$11,729,697
Expenses	\$8,799,521	\$9,467,130
Net Income	\$1,976,002	\$2,262,567

Source: COPN Request No. VA-8583

Also with regard to socioeconomic barriers to access to services, DCOPN notes that, according to the most recent U.S. Census data, Spotsylvania, the locality in which SRMC is located, had a poverty rate of 6.6%, a percentage significantly less than the statewide average of 10.7% (Table 9).

Table 9. Statewide and PD 16 Poverty Rates

Locality	Poverty Rate
Virginia	10.7%
Caroline	9.6%
King George	5.9%
Spotsylvania	6.6%
Stafford	5.4%
Fredericksburg City	16.9%

Source: U.S. Census Data (census.gov)

The most recent Weldon-Cooper data projects a total PD 16 population of 441,075 by 2030 (**Table 10**). This represents an approximate 34.57% increase in total population from 2010-2030. Comparatively, Weldon-Cooper projects the total population of Virginia to increase by only 16.63% for the same period. With regard to Spotsylvania specifically, Weldon-Cooper projects a population growth increase of 29.11% from 2010 to 2030. Regarding the 65 and older age cohort for PD 16, Weldon-Cooper projects a much more rapid increase in population growth (an approximate 151.5% increase from 2010 to 2030) (**Table 11**). 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. With regard to Spotsylvania specifically, Weldon-Cooper projects the 65 and older age cohort to increase by 148.6% from 2010 to 2030.

Table 10. Statewide and PD 16 Total Population Projections: 2010-2030

Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Virginia	8,001,024	8,765,502	8.17%	9,331,666	7.82%	16.63%
Caroline	28,545	30,740	7.69%	34,821	13.28%	21.99%
King George	23,584	23,584	0.00%	31,053	31.67%	31.67%
Spotsylvania	122,397	136,192	11.27%	158,025	16.03%	29.11%
Stafford	128,961	154,093	19.49%	183,161	18.86%	42.03%
Fredericksburg City	24,286	29,403	21.07%	34,015	15.69%	40.06%
TOTAL PD 16	327,773	374,012	14.11%	441,075	17.93%	34.57%

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

Table 11. Statewide and PD 16 Total Population Projections Age 65+: 2010-203
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Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Caroline	3,744	5,369	43.41%	6,729	25.33%	79.74%
King George	2,397	3,870	61.46%	5,547	43.32%	131.41%
Spotsylvania	12,114	21,090	74.10%	30,113	42.78%	148.58%
Stafford	9,464	17,342	83.24%	27,680	59.61%	192.48%
Fredericksburg City	2,413	2,946	22.11%	3,690	25.22%	52.91%
TOTAL PD 16 65+	30,132	50,618	67.99%	75,789	49.73%	151.52%

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

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

COPN Request No. VA-8584: Mary Washington Hospital, Inc. (MWH)

Geographically, MWH is centrally located in Fredericksburg, located off State Route 1 and only a 2.2 mile drive from Interstate 95. MWH is accessible from the principal highway of Interstate 95 via State Route 3 or State Route 17. Mary Washington Healthcare contributes to the public transportation program, the Fredericksburg Regional Transit System, to improve access options for all PD residents.

As previously noted, and as will be discussed in more detail later in this staff analysis report, DCOPN notes that cardiac cath services are well within a 60-minute drive one way under normal conditions of 95% of the population of PD 16. Furthermore, DCOPN notes that the applicant is a current provider of this service. Accordingly, DCOPN contends that approval of the proposed project is not likely to improve geographic access to services in any meaningful way.

Regarding socioeconomic barriers to access to the applicant's services, DCOPN again notes that in 2019, the average amount of charity care provided by HPR I facilities was 3.0% of all reported total gross patient services revenues (Table 7). The Pro Forma Income Statement provided by the applicant (Table 12) does not anticipate a charity care contribution, however DCOPN notes that should the proposed project be approved, it would be subject to the 2.4% system-wide charity care condition currently in place for MWH. DCOPN further notes that this condition contains a provision allowing for the reassessment of the charity care rate once more reliable data regarding the full impact of Medicaid expansion in the Commonwealth becomes available.

Table 12. MWH Pro Forma Income Statement

	Year 1 (2024)	Year 2 (2025)
Net Revenue	\$45,318,132	\$47,317,942
Total Direct Expenses	\$33,212,224	\$35,522,149
Net Revenue less Direct Expenses	\$12,105,908	\$11,795,793
Indirect Expenses	\$4,981,834	\$5,328,322
Net Income	\$7,124,074	\$6,467,470

Source: COPN Request No. VA-8584

Also with regard to socioeconomic barriers to access to services, DCOPN notes that, according to the most recent U.S. Census data, the City of Fredericksburg, the locality in which MWH is located, had a poverty rate of 16.9%, a percentage nearly double that of the statewide average of 10.7% (**Table 9**).

DCOPN again notes that the most recent Weldon-Cooper data projects a total PD 16 population of 441,075 by 2030 (Table 10). This represents an approximate 34.57% increase in total population from 2010-2030. Comparatively, Weldon-Cooper projects the total population of Virginia to increase by only 16.63% for the same period. With regard to Fredericksburg specifically, Weldon-Cooper projects a population growth increase of 40.06% from 2010 to 2030. Regarding the 65 and older age cohort for PD 16, Weldon-Cooper projects a much more rapid increase in population growth (an approximate 151.5% increase from 2010 to 2030) (Table 11). 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. With regard to Fredericksburg specifically, Weldon-Cooper projects the 65 and older age cohort to increase by only 52.9% from 2010 to 2030.

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 proposed project will meet the needs of the 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;

COPN Request No. VA-8583: Spotsylvania Regional Medical Center, Inc. (SRMC)
The applicant provided numerous letters of support for the proposed project. Collectively, these letters addressed the following:

- The project will improve the availability of catheterization services at SRMC and allow the applicant to continue providing timely, high-quality care for its patients.
- Because of the range of services available in SRMC's existing cath lab, and the high quality of those services, SRMC's existing lab is highly utilized. High volumes adversely impact patient access and the availability of these important services, both for patients with scheduled procedures and with acute or emergent needs. The expansion of SRMC's cardiac cath service with the addition of a second lab would alleviate these availability issues and allow the applicant to continue providing patients with the high-quality care they deserve without being delayed by limited access to SRMC's existing cath lab.
- High demand directly affects the availability of services to patients, for many of whom
 timely diagnosis and treatment is critical for positive outcomes. For example, delays in
 treating a heart attack patient caused by an occupied cath lab can cause extensive, permanent
 damage to the patient's cardiac muscle tissue that can ultimately lead to heart failure.

DCOPN is unaware of any opposition to the proposed project.

COPN Request No. VA-8584: Mary Washington Hospital, Inc. (MWH)

The applicant provided numerous letters in support of the proposed project. Collectively, these letters addressed the following:

- In the last few years, a lot of open-heart procedures are now being done in a minimally invasive way in the cardiac cath lab. Aortic valve replacement, mitral valve repair, watchman devise, massive and sub massive pulmonary embolism rescue, to name a few. As MWH is doing more and more of these complex procedures in an area that is seeing rapid population growth, there is a huge strain on its cath labs.
- The cardiac cath labs at MWH have seen continued growth from 2015 to 2019 and the volume expected for 2021 will be much higher than experienced in prior years. The labs at MWH have consistently surpassed the capacity thresholds set by the State.
- MWH provides the full continuum of care for cardiac patients in PD 16 as it is the only
 provider in PD 16 with the ability to provide cardiac surgery back up for high-risk, complex
 patients. Without the addition of a cardiac cath lab at MWH, the laboratories can expect
 greater challenges to meet accessibility expectations for PD 16.

Public Hearing

DCOPN conducted the required public hearing for the proposed projects on October 20, 2021. Due to the ongoing COVID-19 pandemic and at the request of the applicants, the hearing was conducted telephonically. A total of ten people called-in to the hearing, none of which elected to speak. Seven individuals indicated support for the SRMC project, while none indicated opposition. Similarly, three individuals indicated support for the MWH project, while none indicated opposition.

(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;

COPN Request No. VA-8583: Spotsylvania Regional Medical Center, Inc. (SRMC)

As previously noted, SRMC has experienced a noticeable increase in total cardiac cath laboratory utilization over the past five years and operated at 103% of the SMFP threshold for expansion in 2019. Furthermore, DCOPN notes that while SRMC is part of the HCA Health System, no other HCA facility operates cardiac cath laboratories in PD 16. Accordingly, DCOPN concludes that no existing capacity within the HCA Health System is reasonably available for transfer and thus, the applicant has adequately demonstrated a unique institutional need for expansion. Accordingly, DCOPN contends that no reasonable alternative to the proposed project exists.

COPN Request No. VA-8584: Mary Washington Hospital, Inc. (MWH)

As previously noted, MWH has experienced a noticeable increase in total cardiac cath laboratory utilization over the past five years and operated at 112% of the SMFP threshold for expansion in 2019. However, DCOPN notes that the existing cardiac cath laboratory at Stafford Hospital Center, also part of the Mary Washington Health System, operated at only 31% of the SMFP threshold for expansion in 2019, indicating that ample capacity exists within the health system to

care for MWH's patient population. DCOPN further notes that Stafford Hospital Center is located only 9.2 miles (approximately 18 minutes' drive time) from MWH and is not located in a geographically remote location. Accordingly, it could be argued that transferring the existing Stafford Hospital Center lab to MWH would result in a more efficient distribution of cardiac cath services within the PD 16 Mary Washington Health System, without significantly inconveniencing or disadvantaging Stafford Hospital Center's patient population. However, this transfer, as described, would result in the elimination of the cardiac cath service at Stafford Hospital Center. However, DCOPN does conclude that due to MWH's proximity to Stafford Hospital Center, redirecting appropriate MWH cardiac cath cases to Stafford Hospital Center is a reasonable alternative to the proposed project, as doing so would alleviate the overutilization of the MWH labs while simultaneously improving utilization at Stafford Hospital Center.

(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 I designated by the Virginia Department of Health to serve as Health Planning Agency for PD 16. Therefore, this consideration is not applicable to the review of either proposed project.

(iv) Any costs and benefits of the proposed project;

COPN Request No. VA-8583: Spotsylvania Regional Medical Center, Inc. (SRMC)
As illustrated in **Table 5**, the total projected capital cost of the proposed project is \$99,556, the entirety of which will be funded using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with this project. DCOPN concludes that the costs for the proposed project are reasonable and consistent with previously approved projects similar in clinical scope (COPN No. VA-4709 authorized the addition of one cardiac cath lab, involved the cosmetic renovation of existing space, and had a capital cost of \$94,300).

With regard to benefits of the proposed project, the applicant reiterates that there is a unique institutional need for the additional cath lab as the existing lab has operated above 100% of the SMFP threshold for expansion for the last two years. The applicant states that approval of the proposed project is necessary for SRMC to meet the needs of its patients.

COPN Request No. VA-8584: Mary Washington Hospital, Inc. (MWH)

As illustrated in **Table 6**, the total projected capital cost of the proposed project is \$3,521,088, the entirety of which will be funded using the accumulated reserves of the applicant. Accordingly, there are not financing costs associated with this project. DCOPN concludes that the costs for the proposed project are reasonable and consistent with previously approved projects similar in clinical scope (COPN No. VA-4604 authorized the addition of one cardiac cath lab, involved construction, and had a capital cost of \$4,361,027; COPN No. VA-4586 authorized the addition of one cardiac cath lab, involved construction, and had a capital cost of \$1,523,000.

With regard to benefits of the proposed project, the applicant reiterates that there is a unique institutional need for the additional cath lab as the existing lab is no longer capable of adequately serving its patient population.

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

COPN Request No. VA-8583: Spotsylvania Regional Medical Center, Inc. (SRMC)

The applicant has provided assurances that cardiac cath services will be accessible to all patients, regardless of financial considerations. Furthermore, as previously discussed, the Pro Forma Income Statement provided by the applicant anticipates a charity care contribution equal to 4.16% of gross revenues derived from cardiac cath services at SRMC, an amount greater than the average HPR I contribution. However, as already discussed, recent changes to §32.1-102.4B of the Code of Virginia now require DCOPN to place a charity care condition on all applicants seeking a COPN. For this reason, DCOPN recommends that the proposed project, if approved, be subject to a 4.16% charity care condition to be derived from total cardiac cath gross patient services revenue. DCOPN again notes that its recommendation includes a provision allowing for the reassessment of the charity care rate at such time as more reliable data becomes available regarding the full impact of Medicaid expansion in the Commonwealth.

COPN Request No. VA-8584: Mary Washington Hospital, Inc. (MWH)

The applicant has provided assurances that cardiac cath services will be accessible to all patients, regardless of financial considerations. Furthermore, as previously discussed, should the proposed project be approved, it would be subject to the 2.4% system-wide charity care condition currently in place for MWH. DCOPN further notes that this condition contains a provision allowing for the reassessment of the charity care rate once more reliable data regarding the full impact of Medicaid expansion in the Commonwealth becomes available.

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

Section 32.1-102.2:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop, by November 1, 2022, recommendations for a comprehensive State Health Services Plan (SHSP). In the interim, DCOPN will consider the consistency of the proposed projects with the predecessor of the SHSP, the State Medical Facilities Plan (SMFP).

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

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

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

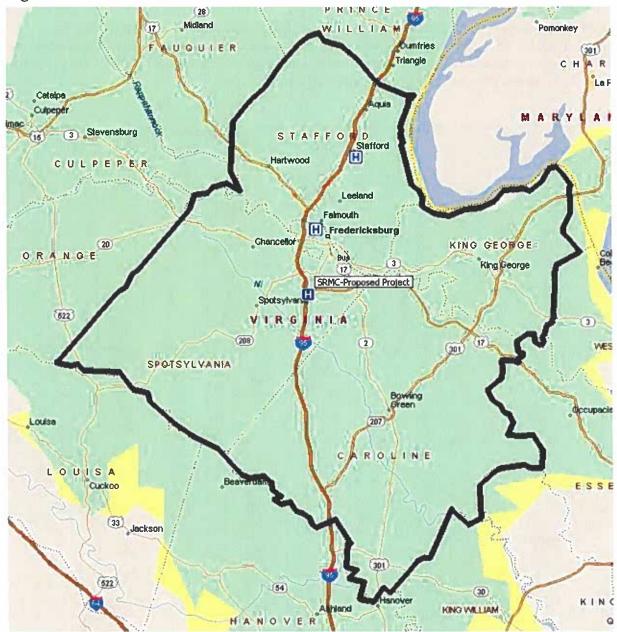
12VAC5-230-380. Travel time.

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.

COPN Request No. VA-8583: Spotsylvania Regional Medical Center, Inc. (SRMC)

The heavy black line in **Figure 1** identifies the boundaries of PD 16. The blue "H" sign marks the location of the proposed project, while the white "H" signs mark the locations of all other existing PD 16 providers of cardiac cath services. The yellow shading illustrates the area that is within a 60-minute drive under normal driving conditions of SRMC, but not within the same drive time of other existing cardiac cath services in PD 16. The green shading illustrates the area that is within a 60-minute drive under normal driving conditions of all other existing cardiac cath services in PD 16. Based on the amount and location of this shading, it is evident that cardiac cath services are already well within a 60 minute drive under normal condition for nearly all residents of PD 16. Furthermore, DCOPN again notes that the applicant is a current provider of cardiac cath services, and accordingly, approval of the proposed project would not improve geographic access to this service for the residents of PD 16 in any meaningful way. However, as the applicant cites an institutional need for the proposed additional lab, DCOPN contends that geographic access is not the factor that prevents the SRMC patient population from receiving timely access to care.

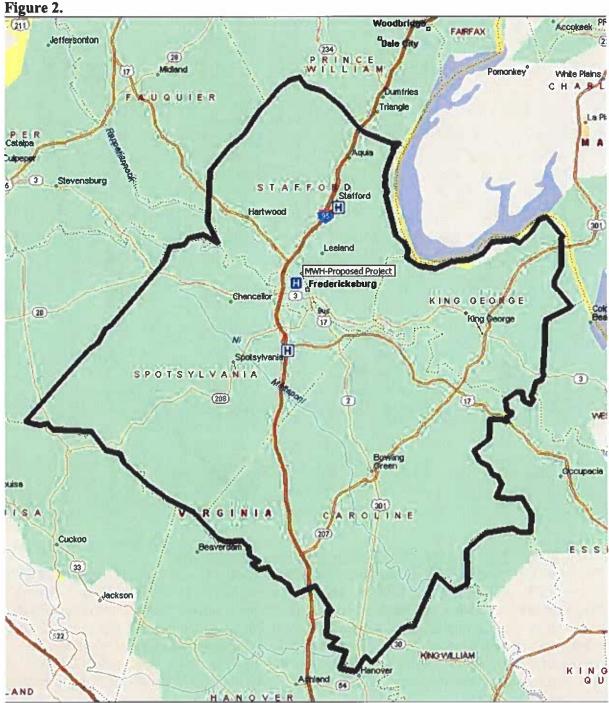
Figure 1.



COPN Request No. VA-8584: Mary Washington Hospital, Inc. (MWH)

The heavy black line in **Figure 2** identifies the boundaries of PD 16. The blue "H" sign marks the location of the proposed project, while the white "H" signs mark the locations of all other existing PD 16 providers of cardiac cath services. The yellow shading illustrates the area that is within a 60-minute drive under normal driving conditions of MWH, but not within the same drive time of other existing cardiac cath services in PD 16. The green shading illustrates the area that is within a 60-minute drive under normal driving conditions of all other existing cardiac cath services in PD 16. Based on the amount and location of this shading, it is evident that cardiac cath services are already

well within a 60 minute drive under normal condition for nearly all residents of PD 16. Furthermore, DCOPN again notes that the applicant is a current provider of cardiac cath services, and accordingly, approval of the proposed project would not improve geographic access to this service for the residents of PD 16 in any meaningful way. However, as the applicant cites an institutional need for the proposed additional lab, DCOPN contends that geographic access is not the factor that prevents the MWH patient population from receiving timely access to care.



12VAC5-230-390. 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; and
 - 3. The utilization of existing services in the health planning district will not be significantly reduced.
- 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.
- 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 of 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.

Neither applicant is proposing to establish a new cardiac cath service, but rather are proposing to expand existing services, citing an institutional need. Accordingly, this provision is not applicable to either proposed project.

12VAC5-230-400. Expansion of services.

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

- 1. 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
- 2. 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.

COPN Request No. VA-8583: Spotsylvania Regional Medical Center, Inc. (SRMC)

As illustrated in **Table 3**, utilization of the cardiac cath service at SRMC increased by nearly half regarding total DEPs between 2015 and 2019. The cardiac cath service reached a utilization level of 103% in 2019 (**Table 1**), based on 1,200 diagnostic equivalent procedures per laboratory as advocated by the SMFP expansion standard for the applicant's existing cardiac cath service. Based on data provided by the applicant, SRMC's cardiac cath lab performed 1,287 DEPs in 2020, operating at approximately 107% of the SMFP expansion standard. Furthermore, the applicant anticipates that SRMC's expanded cardiac cath service will perform 1,611 DEPs in the first year of

operation, and 1,737 DEPs in the second year of operation. Given the consistent increase in utilization at SRMC in recent years, and considering the projected population growth for PD 16, DCOPN concludes that the applicant's projections are reasonable and accordingly, concludes that the applicant has satisfied this standard.

COPN Request No. VA-8584: Mary Washington Hospital, Inc. (MWH)

As illustrated in **Table 3**, utilization of the cardiac cath service at MWH has increased by approximately 28.5% regarding total DEPs between 2015 and 2019. The cardiac cath service reached a utilization level of 112% diagnostic equivalent procedures per laboratory as advocated by the SMFP expansion standard for the applicant's existing cardiac cath service. Based on data provided by the applicant, MWH's three existing cardiac cath labs performed 3,904 DEPs in 2020, operating at approximately 108% of the SMFP expansion standard. Furthermore, the applicant anticipates the MWH's expanded cardiac cath service will perform 5,101 DEPs in the first year of operation, and 5,343 DEPs in the second year of operation. Given the consistent increase in utilization at MWH in recent years, and considering the projected population growth for PD 16, DCOPN concludes that the applicant's projections are reasonable and accordingly, concludes that the applicant has satisfied this standard.

12VAC5-230-410. Pediatric cardiac catheterization.

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

- 1. 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;
- 2. 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;
- 3. The utilization of existing pediatric cardiac catheterization laboratories in the health planning district will not be reduced below 100 procedures per year.

Neither applicant is proposing to perform pediatric cardiac cath procedures. Accordingly, this provision is not applicable to either proposed project.

12VAC5-230-420. Nonemergent 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 cardiac catheterization programs will be required to participate in the Virginia Cardiac Services Quality Initiative and the Virginia Heart Attack Coalition.

As neither applicant is proposing to provide only simple therapeutic cardiac catheterization, this provision is not applicable to either proposed project.

12VAC5-230-430. 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.

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.

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

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.

Each applicant has provided assurances that cardiac cath services at each respective facility will have a medical director who is board certified in cardiology and has clinical experience in performing physiologic and angiographic procedures. Furthermore, each applicant has provided assurances that cardiac cath services at each respective facility will be under the direct supervision of one or more qualified physicians having clinical experience in performing physiologic and angiographic procedures.

The SMFP also contains criteria/standards for when competing applications are received. They are as follows:

Part 1 Definitions and General Information

12VAC5-230-60. When competing applications received.

In reviewing competing applications, preference may be given to the applicant who:

- 1. Has an established performance record in completing projects on time and within the authorized operating expenses and capital costs;
- 2. Has both lower capital costs and operating expenses than his competitors and can demonstrate that his estimates are credible;
- 3. Can demonstrate a consistent compliance with state licensure and federal certification regulations and a consistent history of few documented complaints, where applicable; or
- 4. Can demonstrate a commitment to serving his community or service area as evidenced by unreimbursed services to the indigent and providing needed but unprofitable services, taking into account the demands of the particular service area.

COPN Request No. VA-8583: Spotsylvania Regional Medical Center, Inc. (SRMC)

Based on an analysis of previous DCOPN projects, SRMC generally has a history of completing projects on time and within the authorized capital costs. With respect to the proposed project, the

capital costs (\$99,556) are comparatively much lower than the MWH project; however, DCOPN notes that the projects do vastly differ in clinical scope. DCOPN is unaware of any ongoing or extraordinary documented cardiology service complaints involving this applicant. DCOPN further observes that with regard to the anticipated charity care contribution, MWH did not propose an anticipated charity care contribution and accordingly, the applicant's projected contribution of 4.16% of gross patient services revenue is higher than that of MWH and also the HPR I average for 2019.

COPN Request No. VA-8584: Mary Washington Hospital, Inc. (MWH)

Based on an analysis of previous DCOPN projects, MWH generally has a history of completing projects on time and within the authorized capital costs. With respect to the proposed project, the capital costs (\$3,521,088) are comparatively much higher than the SRMC project; however, DCOPN notes that the projects do vastly differ in clinical scope. DCOPN is unaware of any ongoing or extraordinary documented cardiology service complaints involving this applicant. DCOPN further observes that with regard to the anticipated charity care contribution, the 2.4% system-wide condition currently in place for MWH is lower than both the HPR I average, and the amount anticipated by the SRMC.

Conclusion

Due to the difference in clinical scope of the projects, DCOPN contends that neither applicant deserves preference with regard to lower capital costs. With regard to charity care contributions, DCOPN contends that SRMC deserves favorable preference for its demonstrated commitment to providing a higher level of charity care. As both applicants have a history of on time, on budget delivery, DCOPN concludes that neither applicant deserves preference regarding completing projects on time and within the approved capital budget or with respect to meeting state licensure and federal certification regulations.

The SMFP also contains criteria/standards for when institutional expansion is needed. They are as follows:

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 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.
- 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 the institutional need for the proposed project.
- C. This section is not applicable to nursing facilities pursuant to § 32.1-102.3:2 of the Code of Virginia.
- D. Applicants shall not use this section to justify a need to establish new services.

COPN Request No. VA-8583: Spotsylvania Regional Medical Center, Inc. (SRMC)

The SMFP standards for expansion of an existing cardiac cath service are based on the applicant performing 1,200 DEPs per laboratory annually. In 2019, SRMC's cardiac cath service performed 1,230 DEPs, and as such, operated at 103% of the 1,200 DEPs advocated by the SMFP as the minimum utilization level required for justifying an institution specific need to expand a cardiac cath service. The applicant has stated that in 2020, SRMC's existing cardiac cath lab performed 1,287 DEPs. This is 107% of the expansion threshold and represents a 5% increase in utilization from 2019. Because 2020 VHI data is not yet available, DCOPN is unable to quantifiably confirm this data, but based on SRMC's historical data and PD 16 population growth trends, DCOPN contends that the applicant's data appears to be reasonable. DCOPN again notes that as SRMC is the only HCA facility within PD 16, no underutilized capacity is reasonably available for transfer from within the HCA Health System. Accordingly, DCOPN concludes that no reasonable alternative to the proposed project exists and that the applicant has adequately demonstrated a unique institutional need for the proposed expansion.

COPN Request No. VA-8584: Mary Washington Hospital, Inc. (MWH)

In 2019, MRH's three existing cardiac cath labs performed a collective total of 4,026 DEPs (an average of 1,342 DEPs per cardiac cath lab), and as such, operated at 112% of the 1,200 DEPs advocated by the SMFP as the minimum utilization level required for justifying an institutional specific need to expand a cardiac cath service. The applicant stated that in 2020, MWH's existing cardiac cath service performed a collective total of 3,904 DEPs (an average of 1,301 DEPs per cardiac cath lab). This is 108% of the expansion threshold and represents an approximate 3% decrease in utilization from 2019. However, DCOPN notes that while the existing MWH service experienced a slight decrease in utilization from 2019 to 2020, it has consistently operated above capacity in recent years and will likely continue to do so when PD 16 population growth trends are considered.

DCOPN reiterates that the existing cardiac cath laboratory at Stafford Hospital Center, also part of the Mary Washington Health System, operated at only 31% of the SMFP threshold for expansion in 2019, indicating that ample capacity exists within the health system to care for

MWH's patient population. DCOPN further notes that Stafford Hospital Center is located only 9.2 miles (approximately 18 minutes' drive time) from MWH and is not located in a geographically remote location. Accordingly, it could be argued that transferring the existing Stafford Hospital Center lab to MWH would result in a more efficient distribution of cardiac cath services within the PD 16 Mary Washington Health System, without significantly inconveniencing or disadvantaging Stafford Hospital Center's patient population. However, this transfer, as described, would result in the elimination of the cardiac cath service at Stafford Hospital Center. However, DCOPN does conclude that due to MWH's proximity to Stafford Hospital Center, redirecting appropriate MWH cardiac cath cases to Stafford Hospital Center is a reasonable alternative to the proposed project, as doing so would alleviate the overutilization of the MWH labs while simultaneously improving utilization at Stafford Hospital Center. Nonetheless, because this standard explicitly references the reallocation of services, where applicable, and not the redirection of cases to another facility within the health system, DCOPN concludes that the applicant has adequately demonstrated a unique institutional need to expand cardiac cath services at WMH.

Eight 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;

Each applicant is an established provider of cardiac cath services in PD 16. Furthermore, each applicant cites a unique institutional need for the respective proposed expansions. DCOPN notes that neither proposed project would introduce a new service provider or a new service delivery site to PD 16. Accordingly, DCOPN concludes that neither project is intended to, nor likely to, foster institutional competition that benefits the area to be served.

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;

COPN Request No. VA-8583: Spotsylvania Regional Medical Center, Inc. (SRMC) SRMC, while part of the HCA Health System, is the only HCA provider of cardiac cath services in PD 16. A review of the 2019 utilization for SRMC (Table 1) reveals that SRMC's cardiac cath laboratory operated at 103% utilization. As such, SRMC has asserted an institutional need to expand its cardiac cath services. Because SRMC's expanded service would serve those patients already receiving care at SRMC, approval of the proposed project is unlikely to have a noticeable effect on existing services or facilities, apart from the decompression of the volumes on the one existing cardiac cath lab at SRMC.

COPN Request No. VA-8584: Mary Washington Hospital, Inc. (MWH)

MWH, part of the Mary Washington Health System, is one of two facilities with the PD 16 health system inventory to provide cardiac cath services. A review of the 2019 utilization for MWH (**Table 1**) reveals that MWH's existing three cardiac cath labs operated at a collective utilization of 112%. As such, MWH has asserted an institutional need to expand its cardiac cath services. Because MWH's expanded service would serve those patients already receiving care at MWH,

approval of the proposed project is unlikely to have a noticeable effect on existing services or facilities, apart from the decompression of the volumes on three existing cardiac cath labs at MWH. However, DCOPN again notes that Stafford Hospital Center, also within the Mary Washington Health System and located only 9.2 miles from MWH, operated at only 31% of the SMFP threshold for expansion in 2019. While DCOPN concludes that reallocating Stafford Hospital Center's cath lab to MWH is not feasible, it is worth nothing that one reasonable alternative to the proposed project would be for MWH to redirect appropriate cardiac cath cases to Stafford Hospital Center as doing so would decompress the cath labs at MWH while simultaneously improving utilization at Stafford Hospital Center.

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;

COPN Request No. VA-8583; Spotsylvania Regional Medical Center, Inc. (SRMC)

The Pro Forma Income Statement provided by the applicant (**Table 8**) anticipates a net profit of \$1,976,002 by the end of the first full year of operations and \$2,262,567 in year two, illustrating that the proposed project is financially feasible both in the immediate and the long-term. As already discussed, DCOPN contends that the projected capital costs for the proposed project are reasonable and consistent with previously authorized projects similar in clinical scope. The applicant will fund the project entirely using accumulated reserves and accordingly, there are no financing costs associated with this project.

With regard to staffing, the applicant anticipates the need to hire an additional five full-time employees to staff the proposed project, four of which are registered nurse positions. DCOPN notes that this is in addition to the 63 full-time registered nurse positions currently advertised as vacant. However, DCOPN notes that the applicant is an established provider of cardiac cath services with a robust employee recruitment and retention plan. Accordingly, DCOPN does not anticipate that the applicant will have difficulty staffing the proposed project. Furthermore, with regard to the staffing required for this specific project, due to the low number of employees needed, DCOPN does not anticipate that staffing will result in a significant negative impact on existing providers of cardiac cath services in PD 16.

COPN Request No. VA-8584: Mary Washington Hospital, Inc. (MWH)

The Pro Forma Income Statement provided by the applicant (Table 12) anticipates a net profit of \$7,124,074 by the end of the first full year of operations and \$6,467,470 in year two, illustrating that the proposed project is financially feasible both in the immediate and the long-term. While more expensive than the SRMC project, as already discussed, DCOPN contends that the projected capital costs for the proposed project are reasonable and consistent with previously authorized projects similar in clinical scope. The applicant will fund the project entirely using accumulated reserves and accordingly, there are no financing costs associated with this project.

With regard to staffing, the applicant anticipates the need to hire an additional 25.8 (26) full-time employees to staff the proposed project, 12.8 (13) of which are registered nurse positions. DCOPN notes that this is in addition to the 24 full-time registered nurse positions currently advertised as vacant. The applicant is an established provider of cardiac cath services with a

robust employee recruitment and retention. However, due to the large number of staff needed to staff the proposed project, DCOPN does have concern as to the applicant's ability to retain the needed staff as well as with regard to the impact staffing may have on existing providers of cardiac cath services in PD 16.

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

Neither proposed project offers the introduction of new technology that would promote quality, cost effectiveness, or both in the delivery of health care services. However, as many cardiac cath procedures are performed on an outpatient basis, the expansion of either service would provide for the potential for provision of health care services on an outpatient basis. DCOPN again notes that each applicant bases its respective application on a unique institutional need for expansion and that accordingly, the patient population to be served by each proposed project is those patients already receiving care at SRMC and MWH. For these reasons, DCOPN concludes that approval of either proposed project would result in timelier patient treatment.

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

Not applicable. Neither applicant is a teaching hospital or affiliated with a public institution of higher education or medical school in the area to be served. Neither proposed project would contribute to the unique research, training, or clinical mission of a teaching hospital or medical school.

DCOPN Staff Findings and Conclusions

COPN Request No. VA-8583: Spotsylvania Regional Medical Center, Inc. (SRMC) SRMC proposes to expand its existing cardiac cath service through the addition of one new cardiac cath lab. The projected capital cost of the proposed project total \$99,556, the entirety of which will be funded using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with the proposed project. DCOPN concludes that these costs are reasonable and consistent with previously approved projects similar in clinical scope. Additionally, the Pro Forma Income Statement provided by the applicant indicates that the proposed project would contribute to the overall profitability of SRMC's cardiac cath program both in the immediate and the long-term.

The applicant has provided a projected opening date within ten months of COPN issuance.

SRMC's existing cath lab operated at 103% of the SMFP threshold for expansion in 2019. Furthermore, as no other HCA Health System facility provides cardiac cath services in PD 16, DCOPN concludes that no reasonable alternative to the proposed project exists. Accordingly, DCOPN concludes that the applicant as adequately demonstrated a unique institutional need for the proposed expansion. Should the Commissioner approve the proposed project, DCOPN recommends a charity care condition equal to the 4.16% anticipated by the applicant, to be derived from cardiac cath gross patient services revenue at SRMC.

COPN Request No. VA-8584: Mary Washington Hospital, Inc. (MWH)

MWH proposes to expand its existing cardiac cath service through the addition of one new cardiac cath lab. The projected capital cost of the proposed project total \$3,521,088, the entirety of which will be funded using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with the proposed project. While the capital costs for the MWH project are substantially more than the SRMC project, DCOPN notes that the two projects differ in clinical scope. When compared to previously approved projects similar in clinical scope, the costs for the MWH project appear to be reasonable. Additionally, the Pro Forma Income Statement provided by the applicant indicates that the proposed project would contribute to the overall profitability of MWH's cardiac cath program both in the immediate and the long-term. The applicant has provided a projected opening date of January 2023.

SRMC's three existing cath labs operated at 112% of the SMFP threshold for expansion in 2019. Stafford Hospital Center, a second Mary Washington Health System facility that provides cardiac cath services in PD 16, operated at only 31% utilization for the same period. DCOPN concludes that because reallocating the underutilized service from Stafford Hospital Center to MWH would result in the elimination of the service at the Stafford facility, doing so is not a reasonable alternative to the proposed project. DCOPN notes that one option would be for the applicant to redirect appropriate cardiac cath cases from MWH to Stafford Hospital Center, which would result in the simultaneous decompression of MWH labs and improved utilization at Stafford Hospital Center. However, because the institutional need provision of the SMFP is explicitly limited to the reallocation of services and not cases, DCOPN concludes that the applicant has adequately demonstrated a unique institutional need for the requested additional cath lab at MWH. Should the Commissioner approve the proposed project, it would be subject to the 2.4% system-wide charity care condition currently in place for MWH.

DCOPN Staff Recommendations

COPN Request No. VA-8583: Spotsylvania Regional Medical Center, Inc. (SRMC)
The Division of Certificate of Public Need recommends conditional approval of Spotsylvania Regional Medical Center, Inc.'s request to add one cardiac catheterization lab for the following reasons:

- 1. The proposed project is generally 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 capital costs are reasonable.
- The proposed project appears economically viable both in the immediate and in the longterm.
- 4. No reasonable alternatives to the proposed project exist.
- 5. The applicant has adequately demonstrated a unique institutional need for the additional cardiac catheterization lab.
- 6. There is no known opposition to the proposed project.
- 7. Approval of the proposed project is not likely to have a significant negative impact on the staffing or utilization of existing PD 16 providers of cardiac catheterization services.

DCOPN's recommendation is contingent upon Spotsylvania Regional Medical Center, Inc.'s agreement to the following charity care condition:

Spotsylvania Regional Medical Center, Inc. will provide cardiac catheterization 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 4.16% of Spotsylvania Regional Medical Center, Inc.'s total patient services revenue derived from cardiac catheterization services 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. Spotsylvania Regional Medical Center, Inc. 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.

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

COPN Request No. VA-8584: Mary Washington Hospital, Inc. (MWH)

The Division of Certificate of Public Need recommends **conditional approval** of Mary Washington Hospital, Inc.'s request to add one cardiac catheterization lab for the following reasons:

- 1. The proposed project is generally 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 capital costs are reasonable.
- 3. The proposed project appears economically viable both in the immediate and in the long-term.
- 4. The applicant has adequately demonstrated a unique institutional need for the additional cardiac catheterization lab.
- 5. There is no known opposition to the proposed project.
- 6. Approval of the proposed project is not likely to have a significant negative impact on the utilization of existing PD 16 providers of cardiac catheterization services.

DCOPN's recommendation is contingent upon Mary Washington Hospital, Inc.'s agreement to the following charity care condition:

Mary Washington Hospital, Inc. will provide cardiac catheterization 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. Such service obligations hall be included in and subject to Mary Washington Healthcare's system-wide charity care condition (as reflected in Mary Washington Healthcare's letter of March 17, 2010) of 2.4% of Mary Washington Hospital, Inc.'s total patient services revenue 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. Mary Washington Hospital, Inc. will accept a revised percentage based on the regional average after such time regional charity 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, 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.

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Rife, Corie <corie.rife@vdh.virginia.gov>

RE:	COPN	Request	No.	VA-8583

1 message

Stallings, Thomas J. <tstallings@mcguirewoods.com> To: "Rife, Corie" <corie.rife@vdh.virginia.gov>

Mon, Nov 22, 2021 at 10:49 AM

Thanks!

From: Rife, Corie <corie.rife@vdh.virginia.gov> Sent: Monday, November 22, 2021 10:43 AM

To: Stallings, Thomas J. <tstallings@mcguirewoods.com>

Subject: Re: COPN Request No. VA-8583

"EXTERNAL EMAIL: use caution with links and attachments"

Same to you, Tom!

On Mon, Nov 22, 2021 at 10:31 AM Stallings, Thomas J. <tstallings@mcguirewoods.com> wrote:

Thanks very much, Corie. Have a great Thanksgiving!

From: Rife, Corie <corie.rife@vdh.virginia.gov> Sent: Monday, November 22, 2021 10:30 AM

To: Stallings, Thomas J. <tstallings@mcguirewoods.com>

Subject: Re: COPN Request No. VA-8583

Hi Tom,

DCOPN agrees that a 3% charity care condition is appropriate for this project. The certificate will reflect 3%.

Best.

Corie

On Mon, Nov 22, 2021 at 9:48 AM Stallings, Thomas J. <tstallings@mcguirewoods.com> wrote:

Corie:

As I mentioned in my voicemail to your office number this morning, Spotsylvania Regional Medical Center (SRMC) accepts the standard charity condition for this project. However, SRMC respectfully submits that the percentage

should be 3.0%, not the 4.16% proposed on the last page of the report. Table 7 on page 5 indicates the most-recent HPR charity average is 3.0% based on the 2019 VHI data.

As the report points out, Attachment V.H.3 of the application used 4.16%. Significantly, Attachment V.H.3 stated:

As a placeholder for purposes of this pro forma, charity was calculated at 4.16% of gross revenues, which Spotsylvania Regional Medical Center calculates to be the HPR average based on most-recent available VHI data.

As you'll recall, we had a similar situation this summer with the "placeholder" language in COPN Request No. VA-8556, and I've attached that e-mail correspondence for reference and convenience. As we discussed, HCA COPN pro formas contain the "placeholder" language in recognition that the applicant may not always have access to the same information as DCOPN or calculate the regional average in the same manner as DCOPN.

Accordingly, SRMC respectfully requests that a 3.0% charity condition be applied to this project. As always, thanks for your help, and I would be happy to discuss by phone if that would be helpful. Best wishes for a wonderful Thanksgiving.

Tom

Thomas J. Stallings

McGuireWoods LLP T: +1 804 775 1007 | M: +1 804 241 1784

From: Megibow, Nicholas <nicholas.megibow@vdh.virginia.gov>

Sent: Friday, November 19, 2021 1:18 PM

To: Stallings, Thomas J. <tstallings@mcguirewoods.com>

Cc: Douglas Harris <doug.harris@vdh.virginia.gov>; Rife Corie kcd68724 <corie.rife@vdh.virginia.gov>

Subject: COPN Request No. VA-8583

Good afternoon Tom,

Attached please find the staff report and cover letter for the above referenced project. Corie is out of the office today, so I am sending you the electronic copy in her stead. A hard copy of these documents will be sent to your office via USPS. Please let me know if you have any issues accessing the documents.

Thanks,

Nick

Please note: Our office is on a remote-work plan in an effort to mitigate the spread of COVID-19. We have full access to our telephones, email and documents. If you need to reach me by telephone, please call my office number - 804-367-2144. Thank you.

Nick Megibow, JD Project Analyst Division of Certificate of Public Need Virginia Department of Health (804) 367-2144

This e-mail from McGuireWoods may contain confidential or privileged information. If you are not the intended recipient, please advise by return e-mail and delete immediately without reading or forwarding to others.

Please note: Our office is on a remote-work plan in an effort to mitigate the spread of COVID-19. We have full access to our telephones, email and documents. If you need to reach me by telephone, please call my office number ~ 804-367-2124. Thank you.

Corie E. Rife, JD

Certificate of Public Need Analyst

Office of Licensure and Certification

Virginia Department of Health

(804) 367-2124

Please note: Our office is on a remote-work plan in an effort to mitigate the spread of COVID-19. We have full access to our telephones, email and documents. If you need to reach me by telephone, please call my office number - 804-367-2124. Thank you.

Corie E. Rife, JD

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