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

January 19, 2022

COPN Request No. VA-8599
Carilion Roanoke Memorial Hospital
Roanoke, Virginia
Establishment of a Medical Care Facility for CT Imaging with One CT Scanner

Applicant

Carilion Medical Center (CMC) is a wholly-owned subsidiary of Carilion Clinic. Carilion Clinic is a not-for-profit 501(c)(3) corporation headquartered in Roanoke, Virginia. CMC is a legal entity that includes two acute care hospitals—Carilion Roanoke Memorial Hospital (CRMH) and Carilion Roanoke Community Hospital (CRCH). CRMH is located in Planning District (PD) 5 within Health Planning Region (HPR) III.

Background

CMC is a tertiary care center in Roanoke, Virginia that operates two acute care hospitals, CRMH and CRCH, as well as several medical office buildings that house physician practices, imaging, lab, and other services. Services currently offered by CMC include level one trauma care, a neonatal intensive care unit, a cancer center, and specialized orthopaedic, neurosurgical, gastroenterological and pediatric services. With regard to computed tomography (CT) specifically, CMC is currently authorized to operate eight CT scanners, all of which are located at CRMH.

According to Virginia Health Information (VHI) data, the 13 CT scanners that were operational in PD 5 in 2019 operated at a collective utilization of 110.8%, or 8,200 procedures per unit (**Table 1**). DCOPN notes that since 2019, four additional CT scanners have been added to the PD 5 inventory, including two at CRMH (authorized pursuant to COPN Request No. VA-04615), as notated in **Table 1** below. DCOPN notes that utilization of CT scanners at hospital-based facilities varied significantly from that of CT scanners located at freestanding facilities in 2019. Specifically, the 10 CT scanners located at hospital-based facilities in PD 5 operated at a collective utilization of 135.9% (10,053 procedures per unit), far exceeding the State Medical Facilities Plan (SMFP) expansion threshold of 7,400 procedures per scanner per year, while utilization of CT scanners located at freestanding facilities operated at a collective utilization of only 27.4% (2,024 procedures per unit) for the same period. DCOPN notes that at the same patient volume, and considering the four additional CTs added to PD 5, resulting collective utilization would approximate 6,270 procedures per unit, or 84.7% utilization.

Table 1. COPN Authorized CT Units and Utilization in PD 5: 2019

Hospital Based Facilities	**Units**	**Procedures**	**Procedures/Unit[1]**	**Utilization[2]**
Carilion Roanoke Memorial Hospital	8*	67,515	11,253	152.1%
LewisGale Hospital—Alleghany	1	6,267	6,267	84.7%
LewisGale Medical Center	4**	26,749	8,916	120.5%
Hospital Based TOTAL and Average	**13[3]**	**100,531**	**10,053**	**135.9%**
Freestanding Facilities	**Units**	**Procedures**	**Procedures/Unit**	**Utilization**
Carilion Imaging Services—Botetourt Ct	1	2,168	2,168	29.3%
Insight Imaging—Roanoke	1	2,884	2,884	39.0%
LewisGale Emergency Center	1	1,021	1,021	13.8%
Roanoke ER***	1	--	--	--
Freestanding TOTAL and Average	**4[4]**	**6,073**	**2,024**	**27.4%**
Grand TOTAL and Average	**17[5]**	**106,604**	**8,200**	**110.8%**

Source: 2019 VHI data and DCOPN records
*COPN No. VA-04615 authorized the addition of two CT scanners, resulting in a total complement of eight. The two additional CT scanners became operational in January 2020 and accordingly, utilization data for this facility has been calculated using 2019 VHI data for the then-existing six CT units.
**COPN No. VA-04755, issued in August 2021, authorized the addition of a fourth CT scanner. As this unit is not yet operational, utilization data for this facility has been calculated using 2019 VHI data for the then-existing three CT units.
***Established pursuant to COPN Request No. VA-04671, issued in September 2019. Not yet operational.

With regard to CMC facilities specifically, the seven CT scanners in operation in 2019 operated at a collective utilization of 134.5% (9,955 procedures per unit), with the six scanners at CRMH operating at a collective utilization of 152.1% (11,253 procedures per unit) (**Table 2**). DCOPN notes that at the same patient volume, and considering the two additional CT scanners added to the CMC complement, resulting utilization would approximate 7,743 procedures per unit, or 104.6% utilization. DCOPN further notes that at the same patient volume, the addition of a tenth unit would result in approximately 6,968 scans per unit, or 94.2% utilization among the collective CMC complement.

[1] Data in this column derived from 2019 VHI data.
[2] Utilization computed using 2019 data. Does not account for inventory additions subsequent to 2019.
[3] Though not included in overall calculations for occupancy, this number reflects additions to PD 5 inventory subsequent to 2019.
[4] Though not included in overall calculations for occupancy, this number reflects additions to PD 5 inventory subsequent to 2019.
[5] Though not included in overall calculations for occupancy, this number reflects additions to PD 5 inventory subsequent to 2019.

Table 2. CMC Authorized CT Units and Utilization: 2019

CMC Facility	Units	Procedures	Procedure/Unit[6]	Utilization[7]
Carilion Roanoke Memorial Hospital	8*	67,515	11,253	152.1%
Carilion Imaging Services—Botetourt Ct	1	2,168	2,168	29.3%
CMC TOTAL/Average	**9[8]**	**69,683**	**9,955**	**134.5%**

Source: 2019 VHI data and DCOPN records
*COPN No. VA-04615 authorized the addition of two CT scanners, resulting in a total complement of eight. The two additional CT scanners became operational in January 2020 and accordingly, utilization data for this facility has been calculated using 2019 VHI data for the then-existing six CT units.

Proposed Project

CRMH seeks approval to add one fixed CT unit to its existing complement by establishing a new freestanding imaging center near, but off the CRMC campus. Upon completion of the proposed project, CRMH would operate eight CT scanners, with the requested ninth scanner operating at the new facility. If approved, the requested CT unit will be located in leased space approximately 0.7 miles away from the main hospital campus. The applicant states that there is no additional space for a CT scanner in existing imaging areas at CMC and furthermore, the project, as proposed, is the most cost-effective method for adding additional needed capacity. The applicant states that the project, as proposed, is intended to redirect CT scans from the main campus to the proposed new location, freeing up the units at CRMH to support all of the services and procedures requiring a hospital setting. The applicant further states that once capacity returns to normal pre-COVID levels, CRMH will have the ability to increase CT capacity and plan for future growth, however in the meantime, the applicant will continue to offer extended hours for its CT services.

The projected capital costs of the proposed project total $1,947,003 (**Table 3**), the entirety of which will be funded using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with this project. The applicant anticipates an October 1, 2022 date of opening.

Table 3. CRMH Projected Capital Costs

Equipment Not Included in Construction Costs	$1,162,000
Lease Expense Over Term of Lease	$785,003
TOTAL Capital Costs	**$1,947,003**

Source: COPN Request No. VA-8599

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the "establishment of a medical care facility described in subsection A." A medical care facility includes "Any specialized center…developed for the provision of…computed tomographic (CT) scanning…"

[6] Data in this column derived from 2019 VHI data.
[7] Utilization computed using 2019 data. Does not account for inventory additions subsequent to 2019.
[8] Though not included in overall calculations for occupancy, this number reflects additions to the CMC inventory subsequent to 2019.

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;**

Geographically, the proposed project will be located at 2132 Franklin Road SW in Roanoke, Virginia. The CRMC campus and the proposed new CT site are each located near Interstate 581 and are on Valley Metro bus routes, which serves the greater Roanoke area. As will be discussed in more detail later in this staff analysis report, CT services currently exist with 30 minutes' drive time for at least 95% of the population of PD 5. Furthermore, as the proposed new location is only 0.7 miles from existing CT services within the CMC Health System, approval of the proposed project is not likely to improve geographic access to services in any meaningful way. However, the applicant states that because existing CMC CT units operate above maximum capacity, wait times for a routine CT as of the time of this report are two and a half to three weeks and that accordingly, geographic access is not the factor that prevents access to quality and timely care.

Regarding socioeconomic barriers to access to the applicant's services, according to regional and statewide data regularly collected by Virginia Health Information (VHI), for 2019, the most recent year for which such data is available, the average amount of charity care provided in HPR III was 1.6% of all reported gross patient services revenues (**Table 4**). More specifically, CMC contributed 2.61% of gross patient services revenue in 2019, an amount larger than the HPR III average. The Pro Forma Income Statement provided by the applicant (**Table 5**) anticipates a charity care contribution of 1.6% of gross revenues derived from CT services at CRMH, an amount consistent with the average HPR III contribution. However, 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 1.6% charity care condition, to be derived from total CT gross patient services revenue, consistent with the HPR III average. DCOPN further notes that this condition contains a provision allowing for the reassessment of the charity rate once more reliable data regarding the full impact of Medicaid expansion in the Commonwealth becomes available.

Table 4. 2019 HPR III Charity Care Contributions

Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Carilion Franklin Memorial Hospital	$151,201,325	$6,677,672	4.42%
Dickenson Community Hospital	$25,351,508	$928,420	3.66%
Lonesome Pine Mt. View Hospital	$390,073,389	$13,498,881	3.46%
Carilion Tazewell Community Hospital	$62,008,894	$2,071,457	3.34%
Carilion New River Valley Medical Center	$738,306,843	$20,469,127	2.77%
Carilion Medical Center	$4,068,259,340	$105,984,180	2.61%
Carilion Giles Memorial Hospital	$102,107,168	$2,603,534	2.55%
Russell County Medical Center	$124,033,055	$2,964,704	2.39%
Norton Community Hospital	$319,225,076	$6,779,613	2.12%
Smyth County Community Hospital	$213,627,381	$4,308,217	2.02%
Johnston Memorial Hospital	$889,740,579	$17,870,544	2.01%
Bedford Memorial Hospital	$129,289,507	$2,513,096	1.94%
Centra Health	$2,600,865,348	$41,780,244	1.61%
Lewis-Gale Medical Center	$2,121,321,310	$21,145,842	1.00%
LewisGale Hospital -- Montgomery	$658,786,131	$5,276,155	0.80%
LewisGale Hospital -- Pulaski	$339,877,654	$2,029,419	0.60%
Clinch Valley Medical Center	$547,087,883	$3,000,603	0.55%
LewisGale Hospital -- Alleghany	$212,218,793	$1,046,051	0.49%
Twin County Regional Hospital	$257,431,228	$1,068,667	0.42%
Buchanan General Hospital	$101,667,920	$403,430	0.40%
Wythe County Community Hospital	$257,623,709	$406,156	0.16%
Memorial Hospital of Martinsville & Henry County	$736,050,736	$1,113,236	0.15%
Danville Regional Medical Center	$965,570,236	-$15,516,656	-1.61%
Total Facilities Reporting			23
Median			1.9%
Total $ & Mean %	**$16,011,725,013**	**$248,422,592**	**1.6%**

Source: VHI (2019)

Table 5. CRMH Pro Forma Income Statement

	Year 1	Year 2
Patient Service Revenue	$102,042,000	$107,143,000
Contractual Allowances and Provision for Bad Debts	($82,579,000)	($87,242,000)
Charity Allowances	($1,633,000)	($1,714,000)
Net Patient Service Revenue	**$17,830,000**	**$18,187,000**
Total Operating Expenses	$6,861,000	$7,113,000
Net Income	**$10,969,000**	**$11,074,000**

Source: COPN Request No. VA-8599
*Figures represent the entire CMC CT service and not solely the additional requested unit.

Also with regard to socioeconomic barriers to access to services, DCOPN notes that, according to the most recent U.S. Census data, Roanoke City, the locality in which CRMH is located and the

locality in which the new facility will also be located, had a poverty rate of 20.8%, a percentage more than double that of the 9.9% statewide average (**Table 6**). DCOPN also notes that within PD 5, four out of seven localities had poverty rates higher than the statewide average.

Table 6. Statewide and PD 5 Poverty Rates

Locality	Poverty Rate
Virginia	9.9%
Alleghany	11.5%
Botetourt	5.7%
Craig	11.2%
Roanoke County	6.5%
Covington City	13.2%
Roanoke City	20.8%
Salem City	9.1%

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

The most recent Weldon-Cooper data projects a total PD 5 population of 284,184 by 2030 (**Table 7**). This represents an approximate 3.4% increase in total population from 2010-2030. Comparatively, Weldon-Cooper projects the total population of Virginia to increase by 16.6% for the same period. With regard to Roanoke City specifically, Weldon-Cooper projects a population growth increase of 5.5% from 2010 to 2030. Regarding the 65 and older age cohort for PD 5, Weldon-Cooper projects a much more rapid increase in population growth. With regard to PD 5 collectively, a 41.8% increase is projected, while an increase of 76.4% is projected statewide. This is significant as this population group typically uses health care resources, including diagnostic imaging services, at a rate much higher than those individuals under the age of 65.

Table 7. Statewide and PD 5 Population Projections

Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Alleghany	16,250	14,950	(8.00%)	13,620	(8.90%)	(16.2%)
Botetourt	33,148	33,387	0.72%	34,484	3.29%	4.0%
Craig	10,380	5,084	(51.02%)	5,020	(1.27%)	(51.6%)
Roanoke County	92,376	94,145	1.91%	97,249	3.30%	5.3%
Covington city	5,961	5,677	(4.76%)	5,281	(6.97%)	(11.4%)
Roanoke city	97,032	100,891	3.98%	102,388	1.48%	5.5%
Salem city	24,802	25,953	4.64%	26,141	0.72%	5.4%
Total PD 5	**274,759**	**280,088**	**1.94%**	**284,184**	**1.46%**	**3.4%**
PD 5 65+	**44,720**	**55,442**	**23.97%**	**63,434**	**14.42%**	**41.8%**
Virginia	8,001,024	8,655,021	8.17%	9,331,666	7.82%	16.6%
Virginia 65+	976,937	1,352,448	38.44%	1,723,382	27.43%	76.4%

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

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;

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

- CRMH has a need for additional diagnostic capacity due to the overutilization of its existing CT units. Adequate CT capacity is required at CMC to support the only Level One Trauma Center in HPR III, as well as other emergency studies and a number of inpatient studies that are not available at other facilities in the region. Adding CT capacity in an outpatient setting will enable more accessibility to this critical diagnostic took and also shift volumes from inside the hospital.

- The last reported average procedure volumes on the existing PD 5CT units exceeded the SMFP threshold. CRMH's last reported procedure volumes indicated that its CT units were operating at 152% of the SMFP threshold in 2019. Since then, CRMH has added two CT scanners and volumes have continued to rise. In FY21, CT volumes at CRMH are at 113% of the SMFP threshold. The proposed addition is needed to begin to alleviate the high volumes and patient wait times.

- Wait time for outpatient CT imaging at CRMC is currently approximately 20 days. These prolonged wait times can cause delays in diagnosis and treatment for patients with serious medical conditions including cancer, cardiovascular/pulmonary disease, neurological disorders, orthopedic injuries and conditions, as well as disorders of the abdomen and pelvis.

- In addition to performing routine CT imaging exams, Carilion also provides specialty CT examinations, many of which are only offered within the planning district at CMC. For example, coronary CT angiography, cardiac CT for structural heart intervention planning including catheter based aortic and mitral valve replacements, CT angiography for advanced interventions through the Carilion aortic center, CT enterography for patients with inflammatory bowel disease, multiphase CT imaging for patients with liver/pancreatic/renal disease, and detailed orthopedic CTs for hip resurfacing and complex scoliosis preoperative planning. In addition, CMC also offers dual-energy CT examinations that have several advantages including tissue characterization (renal stone composition characterization, for example), earlier cancer progression detection, and bone marrow edema studies to detect subtle fractures. Many of these more-than-routine CT examinations take additional time to complete and therefore further increase outpatient CT wait times.

DCOPN is unaware of any opposition to the proposed project.

§32.1-102.6B of the Code of Virginia directs DCOPN to hold one public hearing on each application in a location in the county or city in which the proposed is proposed or a contiguous county or city in the case of competing applications; or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. COPN Request No. VA-8599 is not competing with another project in this batch cycle and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing is held.

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

As will be discussed in more detail later in this staff analysis report, DCOPN calculated a current net surplus of two CT scanners in PD 5. Additionally, as **Table 1** demonstrates, the six CT units in operation at CRMH in 2019 operated at a collective utilization of 152.1% (11,253 procedures per scanner) in 2019, far exceeding the SMFP expansion threshold of 7,400 procedures per unit. Additionally, at the same patient volume and considering the two additional CT scanners not yet operational, DCOPN approximates resulting utilization at CRMH to be 8,439 scans per unit, or approximately 114% utilization. Accordingly, maintaining the status quo is not a viable option. Furthermore, only one other PD 5 CMC Health System facility, Carilion Imaging Services—Botetourt Ct, offers CT services. DCOPN notes that this facility operates one CT scanner and is located approximately 17 miles (22 minutes) away from CRMH. While the CT scanner at the Botetourt facility operated at only 29.3% utilization in 2019, DCOPN contends that relocating this scanner is not a viable option as transferring the CT scanner from the Botetourt facility would effectively result in the closure of that facility, while only partially addressing the institutional need cited by the applicant. For example, by maintaining and combining the procedure volumes for both CRMH and the Botetourt facility (assuming the Botetourt volume would transfer with the unit), and using a CT inventory of nine (reflecting an inventory neutral relocation of equipment), DCOPN calculated a resulting occupancy rate of 104.6%. Accordingly, DCOPN maintains that transferring the CT unit from the Botetourt facility will not fully address the constraints experienced by the applicant and thus, is not a reasonable alternative to the proposed project. Similarly, DCOPN contends that due to the distance between the two facilities, offloading CRMC cases to the Botetourt facility is far less advantageous than the proposed project.

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

Currently there is no organization in HPR III designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 5. Therefore, this consideration is not applicable to the review of the proposed project.

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

As demonstrated by **Table 3**, the projected capital cost of the proposed project is $1,947,003, 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 PD 5 projects similar in clinical scope (COPN No. VA-04755 authorized the addition of one CT unit and had a capital cost of $745,634; COPN No. VA-04671 authorized the establishment of a specialized center for CT imaging with one CT scanner and had a capital cost of $11,045,000; COPN No. VA-04615 authorized the addition of two CT scanners and had a capital cost of $2,815,427; COPN No. VA-04519 authorized the establishment of a specialized center for CT imaging with one CT scanner through the relocation of an existing unit and had a capital cost of $1,183,130).

With regard to benefits of the proposed project, the applicant reiterates that there is a unique institutional need for the additional CT scanner as the existing complement operates above 100% of the SMFP threshold for expansion. The applicant states that the existing complement is no longer capable of adequately serving its patient population and that accordingly, approval of the proposed project is necessary for CRMH to provide timely access to care for its patients.

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

The applicant has provided assurances that CT 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 1.6% of gross revenues derived from CT services at CRMH, an amount consistent with the average HPR III contribution. However, as already discussed, recent changes to §32.16-102.4B 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 1.6% charity care condition, to be derived from total CT gross patient services revenues, consistent with the HPR III average. 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.

(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).

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 in determining a public need for the proposed project.

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

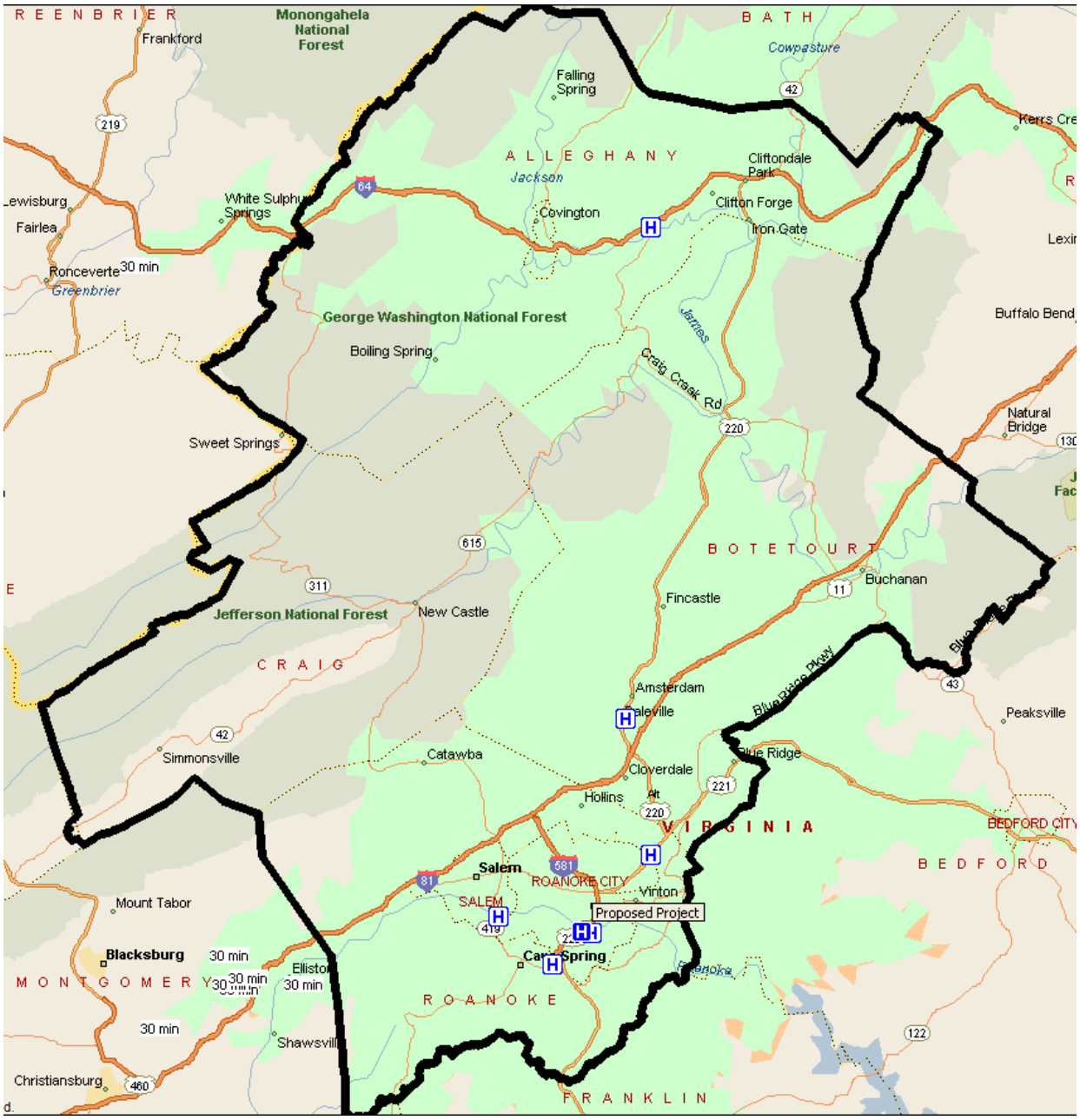
Part II, Article 1 of the State Medical Facilities Plan (SMFP) contains the standards and criteria for the establishment of diagnostic services. They are as follows:

Part II. Diagnostic Imaging Services
Article 1. Criteria and Standards for Computed Tomography

12VAC5-230-90. Travel time.
CT services should be within 30 minutes driving time one way under normal conditions of 95% of the population of the health planning district using a mapping software as determined by the commissioner.

The heavy black line in **Figure 1** identifies the boundaries of PD 5. The blue "H" sign marks the location of the proposed project, while the white "H" sign marks the locations of all other existing PD 5 providers of CT services. The green shading illustrates the area that is within a 30-minute drive under normal driving conditions of existing PD 5 CT services. While the majority of CT services are located in the southern portion of the planning district, based on the amount and location of shading, it appears that CT services are already within a 30-minute drive for at least 95% of the population of PD 5. Furthermore, as the proposed project is located only 0.7 miles from an existing CT service, DCOPN concludes that approval of the proposed project is not likely to improve geographic access to services in any meaningful way nor will it address the current maldistribution of services. However, as the applicant cites an institutional need for the proposed additional CT unit, DCOPN contends that geographic access is no the factor that prevents the CRMH patient population from receiving timely access to care.

Figure 1.


Monongahela National Forest
Frankford
Falling Spring
Cowpasture
Cliftondale Park
Clifton Forge
Iron Gate
Covington
Jackson
White Sulphur Springs
Lewisburg
Fairlea
Ronceverte
Greenbrier
30 min
George Washington National Forest
Boiling Spring
Craig Creek Rd
Sweet Springs
Natural Bridge
Buffalo Bend
Jefferson National Forest
New Castle
Fincastle
Buchanan
Amsterdam
Peaksville
Blue Ridge
Catawba
Simmonsville
Cloverdale
Hollins
Salem
ROANOKE CITY
SALEM
Vinton
Proposed Project
Mount Tabor
Blacksburg
Spring
Shawsville
Christiansburg
ROANOKE
FRANKLIN
BEDFORD
VIRGINIA
CRAIG
BOTETOURT
ALLEGHANY
BATH
MONTGOMERY

12VAC5-230-100. Need for new fixed site or mobile service.

A. No new fixed site or mobile CT service should be approved unless fixed site CT services in the health planning district performed an average of 7,400 procedures per existing and approved CT scanner during the relevant reporting period and the proposed new service would no significantly reduce the utilization of existing providers in the health planning district. The utilization of existing scanners operated by a hospital serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of CT scanners in such health planning district.

As noted in **Table 1**, in 2019, the most recent year for which such data from VHI is available, the 13 CT scanners operational in PD 5 operated at a collective utilization of 110.8% (8,200 procedures per scanner) based on the SMFP threshold of 7,400 CT procedures per scanner per year. Using 2019 VHI data, based on 13 COPN authorized fixed CT scanners in PD 5 and reported CT volume of 106,606 procedures, there is a need for 14.4 (15) CT scanners in PD 5. DCOPN notes that the 2019 VHI data does not take into account the four CT scanners added to the PD 5 inventory subsequent to 2019. Therefore, at present, there is a calculated surplus of two CT scanners in PD 5. However, as will be discussed in more detail later in this staff analysis report, DCOPN contends that the applicant has adequately demonstrated a unique institutional need for the proposed project and accordingly, contends that the project warrants approval despite this calculated surplus.

2019 COPN authorized CT units per VHI data: 13
Calculated Needed CT units: 106,606 total scans ÷ 7,400 = 14.4 (15)
2021 CT scanner inventory: 17
CT scanner surplus: 2

B. Existing CT scanners used solely for simulation with radiation therapy treatment shall be exempt from the utilization criteria of this article when applying for a COPN. In addition, existing CT scanners used solely for simulation with radiation therapy treatment may be disregarded in computing the average utilization of CT scanners in such health planning district.

DCOPN has excluded existing CT scanners used solely for simulation prior to the initiation of radiation therapy from its inventory and average utilization of CT scanners in PD 5.

12VAC5-230-110. Expansion of fixed site service.
Proposals to expand an existing medical care facility's CT service through the addition of CT scanner should be approved when the existing services performed an average of 7,400 procedures per scanner for the relevant reporting period. The commissioner may authorize placement of a new unit at the applicant's existing medical care facility or at a separate location within the applicant's primary service area for CT services, provided the proposed expansion is not likely to significantly reduce the utilization of existing providers in the health planning district.

As will be discussed in more detail later in this staff analysis report, the applicant has demonstrated an institutional need to expand its current CT service. For 2019, the most recent year for which VHI data is available, the six existing COPN approved CT scanners at CRMH operated at a collective utilization of 152.1% (11,253 procedures per unit), far exceeding the 7,400 procedure threshold for expansion. Even considering the two additional CT scanners added pursuant to COPN No. VA-04615, the current CRMH CT inventory operates well above capacity. Specifically, DCOPN calculated a utilization rate of 114% when using 2019 procedure volume and an adjusted inventory of eight CT units. To this point, information provided by the applicant indicates that CRMH's volumes in 2021, thus far, are approximately 6.8% higher than its volumes in 2019 and that as a result, its eight CT units are currently operating at 113% of the SMFP threshold. While DCOPN cannot quantifiably confirm this assertion, it notes that based on historical VHI data for CMC (**Table 8**), and the adjusted calculation discussed above, these assertions appear to be reasonable. Furthermore, as briefly discussed, DCOPN concludes that no available capacity exists within the PD 5 CMC health system for transfer, and that approval of the proposed project would address the overutilization experienced at CRMH without having a significant negative impact on other area providers of CT services.

Table 8. PD 5 CMC Health System Historical CT Utilization

Year	CT Scanners	Total Scans	Scan per Unit	Utilization
2019	7	69,683	9,955	134.5%
2018	7	65,747	9,392	126.9%
2017	7	61,334	8,762	118.4%
2016	7	58,460	8,351	112.9%
2015	7	54,558	7,794	105.3%

Source: VHI (2015-2019)

12VAC5-230-120. Adding or expanding mobile CT services.

A. Proposals for mobile CT scanners shall demonstrate that, for the relevant reporting period, at least 4,800 procedures were performed and that the proposed mobile unit will not significantly reduce the utilization of existing CT providers in the health planning district.

B. Proposals to convert authorized mobile CT scanners to fixed site scanners shall demonstrate that, for the relevant reporting period, at least 6,000 procedures were performed by the mobile scanner and that the proposed conversion will no significantly reduce the utilization of existing CT providers in the health planning district.

Not applicable. The applicant is not seeking authorization to convert an authorized mobile CT scanner to a fixed-site CT scanner.

12VAC5-230-130. Staffing.

CT services should be under the direction or supervision of one or more qualified physicians.

The applicant has provided assurances that CT services at CRMH will be under the direct supervision of one or more qualified physicians.

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.

As previously discussed, for 2019, the most recent year for which VHI data is available, the six existing CT scanners at CRMH operated at a collective utilization of 152.1%. Also as previously discussed, CRMH is part of the CMC Health System, which operates one additional CT scanner (Carilion Imaging Services—Botetourt Ct.) in PD 5. In 2019, that facility's CT scanner operated at only 29.3%. However, despite the low utilization, DCOPN concludes that transferring this scanner is impractical as doing so would effectively result in the closure of that facility, while not fully addressing the institutional need cited by the applicant. To reiterate, by maintaining and

combining the procedure volumes for both CRMH and the Botetourt facility (assuming the Botetourt volume would transfer with the unit), and using a CT inventory of nine (reflecting an inventory-neutral transfer of equipment), DCOPN calculated a resulting occupancy rate of 104.6%. Accordingly, DCOPN maintains that transferring the CT scanner from the Botetourt facility is not a viable option, as doing so would not fully eliminate the institutional need for additional capacity. Furthermore, DCOPN reiterates that due to the distance between the two facilities (approximately a 22 minute drive), redirecting cases from CRMC to the Botetourt facility is less advantageous than the proposed project. Thus, DCOPN maintains that the proposed project is more favorable and that accordingly, no better alternative to the proposed project exists. DCOPN concludes that the applicant has demonstrated an institutional need to expand its current service.

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;

The applicant has cited an institutional need to expand its existing CT service in an effort to decompress the utilization of the existing CT scanners on the hospital campus. As a result, the primary patient population this project would serve is patients who have already chosen CRMH as their care provider. For these reasons, DCOPN contends that the proposed project is not intended to, and is unlikely to, foster institutional competition that would benefit 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;

As previously discussed, DCOPN has calculated a current net surplus of two CT scanners. If approved, the proposed project would increase this surplus to three. However, DCOPN contends that the proposed project warrants approval despite the nominal surplus because CRMH has adequately demonstrated an institutional need to expand. Furthermore, DCOPN reiterates that the primary patient population which would be served by this project are those patients who have already chosen CRMH as their care provider. Accordingly, while approval of the proposed project may result in some impact to neighboring providers, DCOPN maintains that this impact is not likely to be significant or destabilizing.

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;

As already discussed, DCOPN contends that the projected costs for the proposed project are reasonable and consistent with previously authorized projects similar in clinical scope. Furthermore, the Pro Forma Income Statement (**Table 5**) provided by the applicant anticipates a net profit of $10,969,000 in the first year of operation and $11,074,000 by year two. The applicant will fund the project entirely with 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 9.2 full-time employees in order to staff the proposed project. DCOPN notes that this is in addition to the four positions currently vacant. However, the applicant is a current provider of CT services with a robust employee recruitment and retention program. Accordingly, DCOPN does not anticipate that the applicant will have difficulty staffing the proposed project or that doing so will have a significant negative impact on other PD 5 providers of CT services.

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

The proposed project does not offer the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services. However, the proposed project would increase the provision of services on an outpatient basis as well as improve the delivery of health care services at CRMH by addressing the overutilization of its existing CT scanners. DCOPN again notes that the applicant bases its application on a unique institutional need for expansion and that accordingly, the patient population to be served is those patients already receiving care at CRMH. For these reasons, DCOPN concludes that approval of the 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.

The applicant provided the following with regard to this standard:

> *Carilion Clinic is the primary teaching hospital aligned with the Virginia Tech Carilion School of Medicine (VTCSOM). As a result, the radiologists practicing and interpreting studies for clinical patients at Carilion Clinic are also teaching faculty for medical students rotating through Carilion Clinic's Department of Radiology. Radiology is a core Clerkship rotation for medical students. Further, the experience with computed tomography imaging is one that provides excellence and value specific to clinical application and appropriateness of ordering. Clinical decision support tools available to the students in conjunction with radiologist expertise provide education of evidence based best imaging practice for CT as well as other imaging modalities. As this is key to appropriate clinical use and application of CT for diagnosis, it improves health care for our citizens, as well as benefiting underserved populations. Direct and indirect effects include decrease of inappropriate imaging and the attendant patient risk coupled with increased availability for appropriate indications…*

The rotation and exposure to CT educates medical students regarding application of American College of Radiology (ACR) appropriateness criteria and appropriate ordering of studies for clinical impact for patients; other clinical experience in CT exposure side-by-side with Carilion Clinic radiologists include:

- *Neuro-vascular, use CT images to demonstrate normal and pathological anatomy of the cerebral vasculature and analysis for stroke intervention*
- *Determining staging and restaging of malignancies including, but not limited to hepatic, renal, pancreatic, colorectal, and uterine/ovarian*
- *Colorectal cancer screening through CT colonography*
- *Rapid assessment and diagnosis of the extensive range of traumatic conditions*
- *Pre-operative templating of orthopedic implants*
- *Understanding CT safety issues*
- *Participation in CT related clinical research…*

These experiences for VTCSOM medical students provide a solid foundation in clinical learning for clinical radiology and diagnosis and evaluation with CT, as a core component of that education, which also emphasizes the appropriate utilization of medical imaging. Additionally, VTCSOM is a research medical school with a requirement of completion of a research project for graduation. Multiple students have and are participating in clinical research in radiology. The students learn methodologies unique to imaging research in addition to the principles of medical research as a discipline.

DCOPN Staff Findings and Conclusions

CRMH proposes to expand its existing CT service by establishing a freestanding diagnostic imaging facility with one CT scanner approximately 0.7 miles from the main hospital campus. The applicant states that it intends to redirect outpatient imaging procedures from the main hospital to the new location, thereby addressing the overutilization of the existing scanners at the hospital. The projected capital cost of the proposed project is $1,947,003, 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 finds the total capital costs to be 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 CRMH's CT program both in the immediate and the long-term. The applicant has provided a projected opening date of October 1, 2022.

In 2019, CRMH's six existing CT scanners operated at 152.1% utilization, far exceeding the SMFP expansion threshold of 7,400 CT procedures per scanner per year. DCOPN notes that even considering the two CT scanners subsequently added to the CRMH inventory, CRMH's CT service currently operates above capacity and accordingly, the applicant has demonstrated a unique institutional need to expand. Should the Commissioner approve the proposed project, DCOPN recommends a charity care condition equal to 1.6%, consistent with the HPR III average, to be derived from CT gross patient services revenue.

DCOPN concludes that CRMH's proposed project is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. Additionally, DCOPN notes that there is no known opposition to the proposed project and that approval is not likely to have a significant negative impact on the utilization or staffing of existing facilities.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **conditional approval** of Carilion Roanoke Memorial Hospital's request to establish a medical care facility for CT services with one CT scanner 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. No better alternative to the proposed project exists.

5. The applicant has adequately demonstrated a unique institutional need for the additional CT scanner.

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 5 providers of CT services.

8.

DCOPN's recommendation is contingent upon Carilion Roanoke Memorial Hospital's agreement to the following charity care condition:

Carilion Roanoke Memorial Hospital will provide computed tomography (CT) 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 1.6% of Carilion Roanoke Memorial Hospital's total patient services revenue derived from CT 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. Carilion Roanoke Memorial Hospital 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.

Carilion Roanoke Memorial Hospital will provide CT 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, Carilion Roanoke Memorial Hospital will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.