VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification Division of Certificate of Public Need Staff Analysis

January 19, 2023

COPN Request No. VA-8666

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: the only level one trauma center in the region; a neonatal intensive care unit (NICU); a cancer center; and specialized orthopedic, neurosurgical, gastroenterological and pediatric services. Regarding computed tomography (CT) specifically, CMC is currently authorized to operate eight CT scanners, with authorization to add a ninth CT scanner at an off-site location near the CMC campus (COPN No. VA-04783).

Utilizing the data collected from Virginia Health Information (VHI), the 14 PD 5 scanners available in 2021 (with three additionally approved, two being nonoperational, and one being nonoperational during the reporting timeframe) collectively conducted 127,072 scans, with a collective utilization of 122.7% of the State Medical Facilities Plan utilization standard, or 8,298 procedures per unit (**Table 1**). DCOPN notes that since 2021, one additional CT scanner has been added to the PD 5 inventory located at CRMH (authorized pursuant to COPN No. VA-04783), as notated in **Table 1** below. Additionally, two scanners, one located at Roanoke ER and another at Lewis Gale Medical Center are also in the inventory but not utilized in the calculations as one was not operational until July 2022 and the other awaiting operational status, respectively. Utilization of CT scanners at hospital-based facilities varied significantly from that of CT scanners located at freestanding facilities in 2021. Specifically, the 11 available CT scanners located at hospital-based facilities in PD 5 operated at a collective utilization of 147.3% (10,903 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 32.1% (2,377 procedures per unit) for the same period. At the same patient volume and considering

the one additional CT scanner added to PD 5, one awaiting operational status, and one not included in 2021 data, a collective utilization approximating 7475 procedures per unit, or 100.9% utilization is calculated.

Table 1. COPN Authorized CT Units and Utilization in PD 5: 2021

Hospital Based Facilities	Units	Procedures	Procedures/Unit ¹	Utilization ²
Carilion Roanoke Memorial Hospital	9*	73,026	9,129	123.4%
LewisGale Hospital—Alleghany	1	6,639	6,639	89.7%
LewisGale Medical Center	3**	32,276	10,759	145.4%
Hospital Based TOTAL and Average	13 ³	119,941	10,904	147.3%
Freestanding Facilities	Units	Procedures	Procedures/Unit	Utilization
Carilion Imaging Services—Botetourt	1	1,654	1,654	22.4%
CT				
Insight Imaging—Roanoke	1	3,700	3,700	50.0%
LewisGale Imaging at Brambleton	1	1,777	1,777	24.0%
Lewis Gale Medical Center, Blue Hills	1			
ED***				
Freestanding TOTAL and Average	44	7,131	2,377	32.1%
Grand TOTAL and Average	17 ⁵	127,072	9,077	122.7%

Source: 2021 VHI data and DCOPN records

Regarding CMC facilities specifically, the nine CT scanners in operation in 2021 operated at a collective utilization of 112.1% (8,298 procedures per unit), with the eight scanners at CRMH operating at a collective utilization of 123.4% (9,129 procedures per unit) (**Table 2**). At the same patient volume and considering the one additional CT scanner added to the CMC complement, resulting utilization would approximate 7,468 procedures per unit, or 100.91% utilization. DCOPN further notes that at the same patient volume, the addition of a tenth unit would result in approximately 6,790 scans per unit, or 91.74% utilization among the collective CMC complement. For CRMH, the current approved nine CT scanners, when all are operational and assuming the same procedure quantities, would yield 8,114 procedures per unit, or 109.6% utilization. The addition of

² Utilization computed using 2021 data. Does not account for inventory additions subsequent to 2021.

^{*}COPN No. VA-04783 authorized the addition of one CT scanner at an off-site location, totaling nine CT scanners. The ninth scanner has a target date of opening of October 1, 2022; therefore, the 9th scanner is not included in the data set for 2021.

^{**}COPN No. VA-04755, issued in August 2021, authorized the addition of a third CT scanner. As this unit is not yet operational, utilization data for this facility has been calculated using 2021 VHI data for the then-existing three CT units. ***Lewis Gale Medical Center's CT was operational in July 2022, therefore there was no data for the 2021 calculations and is included in the final count.

¹ Data in this column derived from 2021 VHI data.

³ Though not included in overall calculations for occupancy, this number reflects additions to PD 5 inventory subsequent to 2021.

⁴ Though not included in overall calculations for occupancy, this number reflects additions to PD 5 inventory subsequent to 2021.

⁵ Though not included in overall calculations for occupancy, this number reflects additions to PD 5 inventory subsequent to 2021.

the proposed tenth scanner, assuming the same procedure quantities, would yield 7,303 procedures per scanner, or a 98.7% utilization.

Table 2. CMC Authorized CT Units and Utilization: 2021

CMC Facility	Units	Procedures	Procedure/Unit ⁶	Utilization ⁷
Carilion Roanoke Memorial Hospital	9*	73,026	9,129	123.4%
Carilion Imaging Services—Botetourt Ct	1	1,654	1654	22.4%
CMC TOTAL/Average	108	74,680	8,298	112.1%

Source: 2021 VHI data and DCOPN records

*COPN No. VA-04783 authorized the addition of one CT scanner, resulting in a total complement of none. The additional scanner is not yet operational as of the 2021 data collection; utilization data for this facility has been calculated using 2021 VHI data for the then-existing 8 CT units.

Proposed Project

CRMH seeks approval to add one fixed CT unit to the newly constructed Crystal Spring Tower at CRMH. Upon completion of the proposed project, CRMH would operate ten CT scanners. Crystal Spring Tower (Capital Expenditure Registration No. VA-E-0021), a Medical Office Building (MOB) was designed to accommodate a CT scanner. Consequently, the requested project would not require construction or renovation outside the scope approved in Capital Expenditure Registration No. VA-E-0021. If approved, the requested CT unit will be proximal to emergency, trauma, cardiology, and surgery services at CRMH, allowing for a shared access to a common control room (among emergency, trauma, cardiology, and surgery), improving efficiencies with regards to transportation of patients and access to imaging staff. Utilizing the requested scanner for trauma and more emergent, time-dependent procedures will allow other scanners to meet the needs of inpatient and outpatient CT procedure appointments more adequately. The intention for the proposed CT scanner is to serve the ED and be available for emergent, non-scheduled cases, freeing other CT scanners in the hospital for scheduled procedures. Ultimately, the location of the requested CT scanner will save critical time, costs, and will likely lead to better patient outcomes as a result.

The projected capital costs of the proposed project total \$1,417,931(**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 project will not require construction or renovation costs as those are covered in the construction of Crystal Spring Tower (Capital Expenditure Registration No. VA-E-0021). The applicant anticipates opening of the Crystal Spring Tower in May 2025; the scanner will take approximately 12-18 months after ordering to arrive.

⁶ Data in this column derived from 2021 VHI data.

⁷ Utilization computed using 2021 data. Does not account for inventory additions subsequent to 2021.

⁸ Though not included in overall calculations for occupancy, this number reflects additions to the CMC inventory subsequent to 2021.

Table 3. CRMH Projected Capital Costs

CT Scanner	\$1,379,677
Miscellaneous-Computer desk	\$732
Miscellaneous-Smart Plug Package	\$33,176
Miscellaneous-Outbound Interface	\$4,346
Total Capital Costs	\$1,417,931

Source: COPN Request No. VA-8666

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the "The addition by an existing medical care facility described in subsection A of any new medical equipment for the provision of ... computed tomographic (CT) scanning," 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;

Geographically, the proposed project will be located at 1906 Belleview Ave SE., Roanoke, Virginia, 24014, specifically in the Crystal Spring Tower, reported to be completed in May 2025. The CRMC is located near Interstate 581 and is on Valley Metro bus routes serving 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 project location is within a facility already containing CT services, 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 CRMH CT scanners are not sufficient to meet the needs of the diagnostic and procedural applications and that accordingly, geographic access is not the factor that prevents access to quality and timely care. The applicant states the current wait for an interventional CT scan on the dedicated CT scanner is between 10-14 days, while the wait for a routine scan is 2.5-3 weeks. The CMC currently has only 2 bariatric capable scanners; an advantage of the selected scanner having a larger gantry width of 82 cm, allowing for CT scanning of obese patients. Additionally, the applicant states the proposed CT scanner has significantly improved energy capabilities allowing for the overall dose reduction for larger patients.

Regarding socioeconomic barriers to access to the applicant's services, according to regional and statewide data regularly collected by VHI for 2022, the most recent year for which such data is available, the average amount of charity care provided in HPR III was 0.70% of all reported gross patient services revenues (**Table 4**). More specifically, CRMH contributed 2.54% of gross patient

services revenue in 2020, exceeding the HPR III average. The Pro Forma Income Statement provided by the applicant (**Table 5**) anticipates a charity care contribution of 0.70% of gross revenues derived from CT services at CRMH in Years 1 and 2, 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 0.70% 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. 2020 HPR III Charity Care Contributions

Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Carilion Franklin Memorial Hospital	\$146,159,934	\$3,708,842	2.54%
Bedford Memorial Hospital	\$122,377,242	\$2,357,210	1.93%
Dickenson Community Hospital	\$25,321,849	\$465,722	1.84%
Carilion Tazewell Community Hospital	\$57,945,546	\$956,508	1.65%
Carilion Giles Memorial Hospital	\$107,478,905	\$1,438,902	1.34%
Russell County Medical Center	\$121,070,842	\$1,529,332	1.26%
Wellmont Lonesome Pine Mt. View Hospital	\$372,115,538	\$4,558,248	1.22%
Carilion Medical Center	\$3,983,507,417	\$47,514,964	1.19%
Carilion New River Valley Medical Center	\$711,175,865	\$8,034,717	1.13%
Johnston Memorial Hospital	\$855,313,389	\$7,815,178	0.91%
Norton Community Hospital	\$311,397,944	\$2,789,910	0.90%
Smyth County Community Hospital	\$198,825,769	\$1,746,804	0.88%
Centra Health	\$2,649,888,465	\$20,969,883	0.79%
Lewis Gale Hospital Montgomery	\$680,834,380	\$5,052,836	0.74%
Lewis Gale Medical Center	\$2,312,565,268	\$16,202,296	0.70%
Lewis Gale Hospital Pulaski	\$346,826,376	\$2,140,319	0.62%
Lewis Gale Hospital Alleghany	\$189,090,272	\$708,265	0.37%
Twin County Regional Hospital	\$222,632,986	\$649,064	0.29%
Clinch Valley Medical Center	\$520,600,957	\$946,557	0.18%
Buchanan General Hospital	\$99,508,254	\$105,669	0.11%
Memorial Hospital of Martinsville & Henry County	\$668,028,626	\$582,956	0.09%
Wythe County Community Hospital	\$235,991,599	\$93,569	0.04%
Danville Regional Medical Center	\$910,930,415	-\$19,407,300	-2.13%
Total Facilities Reporting			23
Median			0.9%
Total \$ & Mean %	\$15,849,587,838	\$110,960,451	0.7%

Source: VHI (2020)

Table 5. CRMH Pro Forma Income Statement

	Year 1	Year 2
Patient Service Revenue	\$170,323,000	\$178,935,000
Contractual Allowances and Provision for Bad Debts	(\$139,335,000)	(\$147,275,000)
Charity Allowances	(\$1,192,000)	(\$1,253,000)
Net Patient Service Revenue	\$29,796,000	\$30,407,000
Total Operating Expenses	\$14,384,000	\$17,798,000
Net Income*	\$12,412,000	\$12,612,000

Source: COPN Request No. VA-8666

Concerning 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 CT scanner will also be located, had a poverty rate of 17.7%, a percentage 1.73 times statewide average (**Table 6**). DCOPN also notes that within PD 5, five out of seven localities had poverty rates higher than the statewide average.

Table 6. Statewide and PD 5 Poverty Rates

State	Poverty Rate		
Virginia	10.2%		
Locality	Poverty Rate		
Alleghany	14.0%		
Botetourt	6.7%		
Craig	14.2%		
Roanoke County	9.9%		
Covington City	15.8%		
Roanoke City	17.7%		
Salem City	10.0%		

Source: U.S. Census Data 2021 American Community Survey 1-year Estimates (data.census.gov)

The most recent Weldon-Cooper data projects a total PD 5 population of 284,571 by 2030 (**Table 7**). This represents an approximate 3.57% 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. Considering Roanoke City specifically, Weldon-Cooper projects a population growth increase of 4.62% from 2010 to 2030; however, the 65 and older age cohort for PD 5, Weldon-Cooper projects a much more rapid increase in population growth. The 65 and older population in PD 5 collectively is projected to see a 41.8% increase, while an increase of 76.4% is projected statewide. The projections for the 65 and older cohort are 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.

^{*}Figures represent the CRMH CT services plus the additional requested unit.

Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Alleghany	16,250	14,950	(8.00%)	13,993	(6.40%)	(13.89)
Botetourt	33,148	33,387	0.72%	33,556	0.51%	1.23%
Craig	10,380	5,084	(51.02%)	4,528	(1.09%)	(56.38%)
Roanoke County	92,376	94,145	1.91%	100,027	6.25%	8.3%
Covington city	5,961	5,677	(4.76%)	5,434	(4.28%)	(8.84%)
Roanoke city	97,032	100,891	3.98%	101,514	0.62%	4.62%
Salem city	24,802	25,953	4.64%	25,519	(1.67%)	2.89%
Total PD 5	274,759	280,088	1.94%	284,571	1.60%	3.57%
PD 5 65+	44,720	55,442	23.97%	63,434	14.42%	41.80%
Virginia	8,001,024	8,655,021	8.17%	9,331,666	7.82%	16.60%
Virginia 65+	976,937	1,352,448	38.44%	1,723,382	27.43%	76.40%

Source: U.S. Census, Weldon Cooper Center Projections (December 2021) 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 the only Level One Trauma Center in the area necessitating adequate and timely CT capacity to care for these and other emergency patients. Many of the imaging procedures at CMRH are performed in the setting of time-dependent medical conditions that rely upon the ready availability of CT scanner capacity.
- 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 5 CT 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 2021, 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.

• 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. The volumes of procedures at CMC justify an additional CT scanner to CRMH. An approval of this request would help alleviate the current burden upon the existing CT units.

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-8666 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 one CT scanner in PD 5. Additionally, as **Table 1** demonstrates, the eight CT units in operation at CRMH in 2021 operated at a collective utilization of 123.4% (9,129 procedures per scanner), far exceeding the SMFP expansion threshold of 7,400 procedures per unit. At the same patient volume and considering the one additional CT scanner that is approved but not yet operational, DCOPN approximates resulting utilization at CRMH to be 8,114 scans per unit, or 109.6% 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 (23-28 minutes) away from CRMH. While the CT scanner at the Botetourt facility operated at only 22.4% utilization in 2021, 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 ten (reflecting an inventory neutral relocation of equipment), DCOPN calculated a resulting utilization rate of 100.9%. 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 CRMH cases to the Botetourt facility is far less advantageous than the proposed project. Additionally, the request for the new CT scanner in the Crystal Spring Tower would be mainly utilized for trauma, emergency, and time-sensitive services per the applicant. As the only Level One Trauma Center in the area, having a dedicated ED and emergent cases CT scanner would allow for other CT scanners, including the Botetourt facility to serve scheduled inpatient and outpatient procedures timelier.

(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 \$1,417,931, the entirety of which will be funded using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with this project.

Comparing the proposed project to the following two projects showcases the reasonable expenditure for this type of proposal:

- COPN Certificate No. VA-04797, issued August 22, 2022, approved the establishment of one fixed CT scanner at Woodburn Nuclear Medicine/Metro Region PET Center for \$684,000 in Capital costs.
- COPN Certificate No. VA-04804, issued August 22, 2022, approved the addition of one CT scanner at Carilion New River Valley Medical Center for \$2,254,532 in Capital costs.

As exemplified in comparison to the two projects listed above, the proposal falls within these two costs at \$1,417,931. The project also does not require debt-financing as the project will be utilizing accumulated hospital reserves.

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 as the only Level One Trauma Center in the area.

(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. In 2020, the most recent data available, CRMH reports 2.54% of their gross revenues to be charity, which is greater than the average of HPRIII of 0.7%. Furthermore, as previously discussed, the Pro Forma Income Statement provided by the applicant anticipates a charity care contribution equal to 0.7% 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 0.7% 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;

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;

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

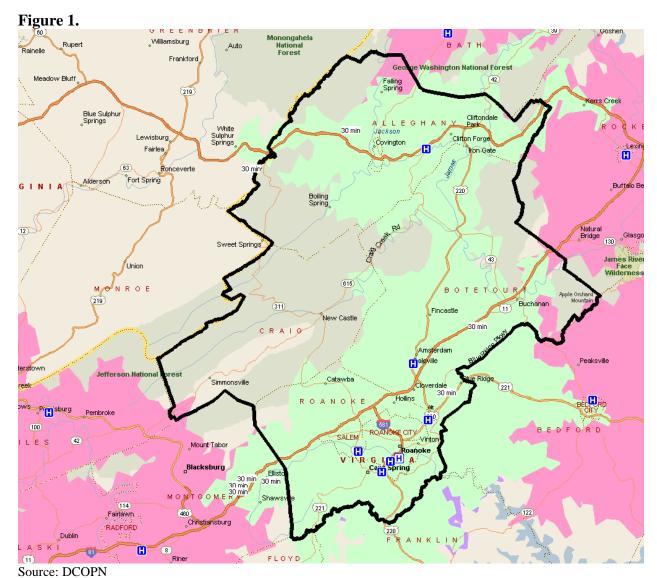
Part II, Article 1 of the State Medical Facilities Plan (SMFP) contains the standards and criteria for the establishment of diagnostic services. They are as follows:

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 white square with the blue "H" is the location of the proposed project, while the blue squares with a white "H" mark the locations of all other existing PD 5 providers of CT services. The light green shading is the area within a 30-minute drive of existing CT providers in PD 5, and the pink shading is the area that is within a 30-minute drive of CT providers in the surrounding planning districts. Most PD 5 CT services are located in the southern portion of the planning district, where the population is concentrated, 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 in the same facility as existing CT services, DCOPN concludes that approval of the proposed project is neither 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 not the factor that prevents the CRMH patient population from receiving timely access to care.



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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.

While this portion of the code is not directly applicable, DCOPN conducted this calculation as another angle with which to assess the community need of an additional scanner.

As noted in **Table 1**, in 2021, the most recent year for which such data from VHI is available, the 15 CT scanners operational in PD 5 at the time operated at a collective utilization rate of 114.5%

(8,471 procedures per scanner) based on the SMFP threshold of 7,400 CT procedures per scanner per year. Using 2021 VHI data, based on 17 COPN authorized fixed CT scanners in PD 5 and reported CT volume of 127,072 procedures, there is a need for 17.17 (18) CT scanners in PD 5. Based upon SMFP threshold standards, PD 5 has an adequate quantity of CT scanners; 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 the calculated surplus.

2021 COPN authorized CT units per VHI data: 17* Calculated Needed CT units: 127,072 total scans ÷ 7,400 = 17.17 (18) 2021 authorized CT scanner inventory: 17

CT scanner shortage: 1

*2021 VHI shows 15, however, COPN records have newer data showing 17 total authorized CT units

There is a calculated projected population growth for PD 5 with a comparatively significant projected growth in the 65 and older community. The current authorized quantity of 17 CT scanners at the 2021 quantity of procedures yields a 95.4% utilization, or 7,060 procedures per scanner. It would be reasonable to consider the plausibility of the procedure quantity increasing at a faster rate than the approved scanners becoming operational will be able to accommodate, leading to demand exceeding capacity.

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 2021, the most recent year for which VHI data is available, the eight existing COPN approved and operational CT scanners at CRMH operated at a collective utilization of 123.4% (9,129 procedures per unit), far exceeding the 7,400-procedure threshold for expansion. Even considering the additional CT scanner added pursuant to COPN No. VA-04783, the current CRMH CT inventory operates well above capacity. Specifically, DCOPN calculated a utilization rate of 109.6% (8,114 procedures

per unit) when using 2021 procedure volume and an adjusted inventory of nine CT units. To this point, information provided by the applicant indicates that CRMH's volumes in 2022, thus far, are approximating the volumes from 2021, indicating a current operation utilization of 123.4% of the SMFP threshold. Applicant indicates the three-year average increase of volume, accounting for Covid-19 impacting scanning volume growth, is 1.3% for inpatient CT volumes and 4.3% for outpatient CT volumes. 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
2021	9	74,680	8,298	112.1%
2020	9	66,710	7,413	100.0%
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 (2015-2021)

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/radiologists.

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 2021, the most recent year for which VHI data is available, the eight existing CT scanners at CRMH operated at a collective utilization of 123.4%. 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 2021, that facility's CT scanner operated at only 22.4%. 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. Additionally, the purpose of the proposed CT scanner and location are of a different nature, specifically to assist in lower CT wait time for other CT scanners in the hospital and utilizing the new scanner primarily for trauma and emergency services patients. The proposed CT scanner will also have capabilities that are more conducive to the trauma and emergency services' needs. To reiterate, by maintaining and combining the procedure volumes for both CRMH and the Botetourt facility from 2021 and using a CT inventory of ten (reflecting an inventory-neutral transfer of equipment), DCOPN calculated a resulting occupancy rate of 100.9%. Accordingly, DCOPN maintains that transferring the CT scanner from the Botetourt facility is not a viable alternative to the project, as doing so would barely eliminate the institutional need for additional capacity, would likely lead to the Botetourt CT facility closure, and would not address the needs of the only Level One Trauma Center in the area. 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.

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 neither benefit nor harm the area to be served. There are no other healthcare facilities with equivalent capabilities that CRMH wholly encompasses within the HPR III.

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 shortage of one scanner in the HPR III. If approved, the proposed project would create an appropriate CT quantity. However, DCOPN contends that the proposed project warrants approval because CRMH has adequately demonstrated an institutional need to expand in addition to being regionally beneficial. 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 \$12,412,000 in the first year of operation and \$12,612,000 by year two. The applicant will fund the project (estimated capital costs of \$1,417,931) entirely with accumulated reserves and accordingly, there are no financing costs associated with this project.

Addressing staffing, the applicant anticipates the need to hire an additional 8.7 full-time employees to staff the proposed project. The applicant is a current provider of CT services with an ongoing employee recruitment and retention program. Carilion posts positions on Carilion's website and on various imaging-related and nursing job boards. Additionally, applicant stated they also contact instructors at local institutions for new hire prospects. Per applicant, CRMH reaches out to education programs with new graduates in the field as a part of their recruitment efforts; therefore, much of their recruitment efforts will not be pulling from other institutions' positions. On Carilion's web site in the "Jobs" section, it is noted that there are 33 radiologic technician (non-ultrasound, non-nuclear medicine) positions in recruitment, 9 of which are specific to CT. There is a nation-wide shortage in healthcare professionals, and staff will be an ongoing concern. There is a potential for recruitment efforts to impact surrounding providers of CT services, but the impact ought to be somewhat mitigated by recruiting from radiologic technician programs.

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, cost effectiveness in the delivery of health care services. However, the proposed project aims to purchase a scanner with the following attributes and benefits: (1) the X.ceed system, manufactured by Siemen's Healthcare, can perform perfusion studies for early stroke detection, (2) perform CT studies of the heart to support the expanding needs of the Carillion Clinic Cardiovascular Institute, (3) has larger gantry width of 82cm to allow CT scanning of obese patients (only 2 other bariatric CT scanners in CRC inventory), (4) has significantly improved energy capabilities allowing for overall dose reduction for larger patients, and (5) will improve the delivery of health care services at CRMH by addressing the overutilization of its existing CT scanners. DCOPN is not recommending conditional approval regarding the specified equipment but acknowledges the benefits of the CT scanner being proposed at this time. 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. By the proposed scanner being utilized by more severe and time-sensitive CT scanning cases, the other CT scanners will have increased ability to support outpatient scanning needs. 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 sideby-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 expanding CT services with one CT scanner within the main hospital campus, specifically in the newly designed Crystal Springs Tower, anticipated to open May 2025. The applicant states that it intends to have centrally located a CT scanner that mainly supports trauma, emergency services, stroke, and cardiovascular programs (those programs that are more time-sensitive). Through having the proposed CT scanner, the other CT scanners in the hospital will be able to better support the outpatient and less time-sensitive patients' needs without having scheduling conflicts due to the time-sensitive cases where seconds can be crucial to lifesaving and life-quality outcomes.

The projected capital cost of the proposed project is \$1,1,417,931, 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 May/Spring 2025.

In 2021, CRMH's eight existing CT scanners operated at 123.4% utilization, far exceeding the SMFP expansion threshold of 7,400 CT procedures per scanner per year. DCOPN notes that even considering the one 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 0.7%, 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 for the addition one CT scanner in the Crystal Spring Tower 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 an extensively negative impact on the staffing or utilization of existing PD 5 providers of CT services due to recruitment efforts focusing on new graduates.

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 0.70% 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.