

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

March 23, 2026

RE: COPN Request No. VA-8863

Carilion Medical Center d/b/a Carilion Roanoke Memorial Hospital

Roanoke, Virginia

Add one additional linear accelerator at Carilion Medical Center

Applicant

Carilion Medical Center (CMC) is a 501(c)(3) Virginia non-stock corporation. CMC is a tertiary care center located in Roanoke, Virginia, Planning District (PD) 5, Health Planning Region (HPR) III. CMC's campus has two hospitals – Carilion Roanoke Memorial Hospital (CRMH) and Carilion Roanoke Community Hospital (CRCH). CMC is a wholly owned subsidiary of Carilion Clinic, a 501(c)(3) Virginia non-stock corporation located in Roanoke, Virginia.

Background

Linear Accelerator

A linear accelerator (LINAC) uses electromagnetic technology (similar to what is used for radar) to accelerate electrons in a part of the accelerator called the “wave guide”; these electrons then collide with a heavy metal target to produce high-energy x-rays.¹ These medical LINACs are most commonly used for external beam radiation treatments for patients with cancer; the beams can be targeted to destroy cancer cells while sparing the surrounding normal tissue from direct contact with the beam.²

According to Virginia Health Information (VHI) data for 2024, the latest such data are available, and DCOPN records, the LINAC inventory in PD 5 consists of four LINACs without SRS/SRT³ capability and two LINACs with SRS/SRT capability, excluding Gamma Knives™ (**Table 1**).

¹ Radiological Society of North America (RSNA) and American College of Radiology (ACR). “Linear Accelerator.” Radiologyinfo.org. Accessed February 1, 2023.

<https://www.radiologyinfo.org/en/info/linac#:~:text=The%20linear%20accelerator%20uses%20microwave,high%20Denergy%20x%20Drays.>

² Radiological Society of North America (RSNA) and American College of Radiology (ACR). “Linear Accelerator.” Radiologyinfo.org. Accessed February 1, 2023.

<https://www.radiologyinfo.org/en/info/linac#:~:text=The%20linear%20accelerator%20uses%20microwave,high%20Denergy%20x%20Drays.>

³ Stereotactic Radiosurgery (SRS) and Stereotactic Radiotherapy (SRT)

Table 1. COPN Authorized Linear Accelerators (Excluding Gamma Knife™) in PD 5

Facility	Lin. Acc. without SRS/SRT	Lin. Acc. with SRS/SRT	Total
Carilion Roanoke Memorial Hospital	2	1	3
LewisGale Medical Center	2	1	3
Total	4	2	6

Source: VHI (2024) and DCOPN Records

Proposed Project

The applicant proposes adding one LINAC without SRS/SRT capabilities to the CMC campus in Roanoke, Virginia. CMC already operates two LINACs without SRS/SRT capabilities and one Cyberknife unit that is exclusively used for SRS. CMC was also approved to add proton-beam therapy under VA-04936, which is expected to be operational in late 2027.

The applicant proposed to purchase and install a TrueBeam Base System 120 MLC 1 Linear Accelerator in a newly constructed building dedicated to cancer services called the Carilion Taubman Cancer Center (CTCC). This project will be part of a larger effort on the part of CMC to consolidate cancer services in a centralized and dedicated space. The CTCC will operate as a department of CRMH. Upon completion of the CCTC all existing radiation therapy equipment on the CMC campus will be relocated to the new building.⁴

The total capital costs of the proposed project are \$3,782,869, of which direct construction costs will only account for \$3,512,869 or 92.9% (**Table 2**). The proposed project will be funded through accumulated reserves of the applicant, therefore, there are no financing costs associated with the proposed project.

Table 2. Capital and Financing Costs

Direct Construction Costs	\$250,000
Equipment Not Included in Construction Contract	\$3,512,869
Architectural and Engineering Fees	\$20,000
Total	\$3,782,869

Source: COPN Request No. VA-8863

Construction for the proposed project is expected to begin January 2027, and to be completed in October 2027. The applicant anticipates an opening date in January 2028.

⁴ All radiation therapy equipment relocation is occurring within the CMC campus and therefore additional COPN certificates are not required.

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the “addition by an existing medical care facility described in subsection A of any new medical equipment for the provision of ... radiation therapy...” A medical care facility includes “[a]ny facility licensed as a hospital.”

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;**

Regarding access and transportation, the applicant stated:

The CMC campus, including the site for the new CTCC, is located off Interstate 581. The CMC campus and surrounding outpatient clinics are easily accessed by residents of Southwest Virginia and surrounding communities, which comprise PD 5, as well as the broader geographic and health planning region.

Valley Metro, located at 3rd Street Station, is the public transportation provider for the Roanoke Valley. Service includes fixed routes, specialized transportation for individuals with disabilities, and special shuttles. Valley Metro also provides bus service between Roanoke and the New River Valley with its Smart Way Bus. The Smart Way Bus is the broader regional public transportation service operated by Valley Metro, linking the Roanoke Valley and the New River Valley for a fare of \$4 each way. The Smart Way also begins service at 3rd Street Station in Roanoke, with stops at lodging facilities, the airport, two park-and-ride lots along Interstate 81, and New River Valley stops.

The Star Line-Trolley Service connects Downtown Roanoke, where the major stops for Amtrak and Valley Metro reside, to the overall campus of CMC. The Star Line-Trolley Service is free and runs every 20 minutes, starting at 7 a.m. and ending at 7.p.m. The trolley network of stops includes CRCH and CRMH, both part of the CMC campus. The trolley also connects patients and visitors to the Carilion Riverside Clinic, located between both hospitals.

For broader access, the Northeast Regional Amtrak train makes daily roundtrips between Roanoke and Washington, D.C., stopping in Lynchburg, Charlottesville, Culpeper, Manassas, Burke Centre, Alexandria, and Washington. The Roanoke stop occurs at 6:20

a.m. daily on Norfolk Avenue, SW, 2 miles from CRMH. From the Amtrak station, the Valley Metro Bus Station.⁵

PD 5 had a population of about 281,000 in 2020 and is projected to decrease by just under 4,000 people (1.3% decrease) between 2020 and 2030. This is less than the population growth rate projected for Virginia during this decade, an increase of 5.8%. The City of Roanoke, where the proposed project is located, is projected to decrease by 0.9% (925 people), between 2020 and 2030 (Table 3). The growth rates projected for 2020-2030 in the 65 and older age group are 20% in the City of Roanoke and 17% in PD 5 as a whole, compared to 26.3% in Virginia (Table 3).

Table 3. PD 5 Population Data Projection (2020-2030)

Locality	2020 Population	2030 Population	Growth 2020-2030	Percent Growth 2020-2030	65+ 2020 Population	65+ 2030 Population	Growth 65+	Percent Growth 65+
Alleghany County	15,223	14,295	-928	-6%	3,933	4,207	+274	+7%
Botetourt County	33,596	33,074	-522	-2%	7,882	9,528	+1,646	+21%
City of Covington	5,737	5,282	-455	-8%	1,201	1,317	+116	+10%
Craig County	4,892	4,539	-353	-7%	1,124	1,280	+156	+14%
Roanoke County	96,929	96,811	-118	-0.1%	21,449	25,494	+4,045	+19%
City of Roanoke	100,011	99,086	-925	-0.9%	17,899	21,438	+3,539	+20%
City of Salem	25,346	24,860	-486	-2%	5,328	6,324	+996	+19%
PD 5	281,734	277,947	-3,787	-1.3%	58,816	68,588	+9,772	+17%
Virginia	8,631,393	9,129,002	497,609	5.8%	1,395,291	1,762,641	367,350	26.3%

Source: Weldon-Cooper

With respect to socioeconomic barriers, the poverty rate of PD 5 (12.3%) is significantly higher than that of Virginia (10.7%) (Table 4). The City of Roanoke, the location of the proposed project has the highest poverty rate in PD 5 at 18.4%.

Table 4. PD 5 Poverty Rates, 2024

Geographic Name	Poverty Rate
Alleghany County	13.9%
Botetourt County	6.3%
City of Covington	17.7%
Craig County	12.3%
Roanoke County	7.2%
City of Roanoke	18.4%
City of Salem	10.4%
PD 5	12.3%
Virginia	10.7%

Source: https://www.census.gov/data-tools/demo/saiper/#/?s_state=51&s_county=&s_district=&s_geography=county

⁵ Source: COPN Request No. VA-8863

CMC accepts all patients regardless of their ability to pay or other considerations. It provided charity care at 0.8% of gross patient revenues in 2024, the latest year for which such data are available. This is above the HPR III average of 0.5% that same year (**Table 5**). The Pro Forma provided by the applicant (**Table 6**) assumes charity care of 0.5% for the proposed project, consistent with the HPR III charity care contribution average in 2024.

In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project receive approval, the project would be conditioned to provide a level of charity care based on gross patient revenues derived from radiation therapy services that is no less than the equivalent average for charity care contributions in HPR III of 0.5%. Pursuant to Code of Virginia language any COPN issued for this project will also be conditioned on the applicant's agreement to accept patients who are the recipients of Medicare and Medicaid.

Table 5. HPR III Charity Care Contributions: 2024

HPR III	Gross Pt Rev	Total Charity Care Provided Below 200%	%
Inpatient Facilities			
Rehabilitation Hospital of Bristol, LLC	21,074,983	594,048	2.8%
Centra Specialty Hospital	49,629,337	1,151,183	2.3%
Carilion Franklin Memorial Hospital	291,774,472	4,126,513	1.4%
Carilion Tazewell Community Hospital	97,063,289	1,035,463	1.1%
Carilion Medical Center	5,523,913,586	43,089,656	0.8%
Carilion New River Valley Medical Center	1,045,584,847	8,284,749	0.8%
LewisGale Hospital-Montgomery	1,028,863,817	8,035,905	0.8%
Carilion Giles Memorial Hospital	241,763,245	1,965,594	0.8%
Lewis-Gale Medical Center	3,633,204,645	25,020,978	0.7%
LewisGale Hospital Pulaski	557,969,215	3,462,675	0.6%
LewisGale Hospital - Alleghany	307,838,577	1,894,786	0.6%
Bedford Memorial Hospital	220,261,406	1,156,200	0.5%
Johnston Memorial Hospital	939,082,042	3,526,000	0.4%
Centra Health	3,572,261,352	12,125,268	0.3%
Wellmont Lonesome Pine Mountain View Hospital	852,382,429	2,640,163	0.3%
Smyth County Community Hospital	216,722,529	604,993	0.3%
Lee County Community Hospital	43,608,193	118,721	0.3%
Dickenson Community Hospital	28,200,560	54,209	0.2%
Russell County Medical Center	137,892,582	161,769	0.1%
Buchanan General Hospital	127,118,204	137,889	0.1%
Sovah Health-Danville	1,253,164,239	288,678	0.0%
Sovah Health-Martinsville	917,943,082	268,214	0.0%
DLP Twin County Regional Healthcare	363,954,973	128,136	0.0%
Clinch Valley Medical Center	829,913,180	191,054	0.0%
Wythe County Community Hospital	415,798,563	100,166	0.0%
Ridgeview Pavilion (Bristol Region)	8,928,438	0	0.0%
Norton Community Hospital			
Total Inpatient Hospitals:			26
HPR III Inpatient Hospital Median			0.4%
HPR III Total Inpatient \$ & Mean %			0.5%
	\$ 22,725,911,785	\$ 120,163,010	

Source: VHI (2024)

DCOPN is not aware of any other geographic, socioeconomic, cultural, or transportation barriers to access to care.

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

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

DCOPN received four letters of support for the proposed project, which stated:

- An additional LINAC is needed to address the growing rates of cancer among the area population.
- The current scanners cannot handle high volumes which is leading to delays in scheduling which disrupts care coordination and can lead to disease progression.
- The new Carilion cancer center will reach patients beyond PD 5 to include southwestern Virginia, West Virginia and North Carolina.

DCOPN did not receive any letters in opposition to the proposed project.

Public Hearing

Section 32.1-102.6 B of the Code of Virginia directs DCOPN to hold one public hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city in the case of competing applications; or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. COPN Request No. VA-8863 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 was held.

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

Neither DCOPN nor the applicant were aware of any reasonable alternatives to the proposed project that would meet the needs of the population in a less costly, more efficient, or more effective manner. The status quo is not a viable alternative to the proposed project because the two non-SRS/SRT capable LINACs that CMC operates were at 143.73% of the SMFP threshold for expansion according to the 2024 VHI data. When combined with the SRS/SRT capable LINAC, the overall utilization for CMC was 99.30%⁶. This will be discussed in further detail later in the report.

While the single SRS/SRT capable unit only reported 5.23% utilization in 2024, neither the applicant nor DCOPN sees shifting capacity to this unit as a viable alternative. As explained in the application, the SRS/SRT capable unit is a highly specialized Cyberknife that is used only for SRS procedures, while the other two non-SRS/SRT units are only used for conventional radiation therapy. As such, the request is for an additional non-SRS/SRT capable LINAC that will only perform conventional radiation therapy.

⁶ Previously DCOPN used “visits” as part of the utilization calculation for Linear Accelerators because that was that was the metric that collected by VHI. Starting with the 2024 VHI report, however, “procedures” were collected as well, which is referenced in the utilization calculations in **12VAC5-230-300**. Going forward, DCOPN will use “procedures” exclusively in all linear accelerator utilization calculations.

(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 shown in **Table 2**, the estimated capital costs of the proposed project are \$3,782,869, of which approximately 92.9% represents equipment costs. This cost is reasonable compared to other similar projects. For example, VA-04934 proposed to add 1 SRS capable linear accelerator for a total cost of \$6,321,025 (87% of which was equipment cost). The proposed project will be funded entirely through accumulated reserves, therefore, there are no financing costs associated with the proposed project.

The applicant identified numerous benefits to the proposed project, including:

- CMC is in need of an additional linear accelerator because the two existing (non-SRS/SRT) machines are over capacity. CMC currently provides over 80% of all linear accelerator procedures in PD 5.
- An additional linear accelerator will reduce overutilization and minimize equipment downtime and interruption of service.
- The population of PD 5 is aging, and an additional linear accelerator will be needed to accommodate the rise in cancer rates that will follow.

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

The Pro Forma Income Statement provided by the applicant includes charity care of 0.5% (**Table 6**). As previously discussed, should the Commissioner approve the proposed project, CMC should be subject to charity care consistent with the HPR III average of 0.5% for radiation therapy services in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

Table 6. Pro Forma Income Statement

	Year 1	Year 2
Gross Patient Revenue	\$123,800,154	\$130,702,012
Contractuals	(\$93,977,860)	(\$99,217,125)
Charity Care	(\$631,381)	(\$666,580)
Net Patient Revenue	\$29,190,913	\$30,818,307
Total Expenses	\$18,167,521	\$19,296,602
Net Operating Income	\$11,023,352	\$11,521,705

Source: COPN Request No. VA-8863

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

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

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 SMFP. They are as follows:

The SMFP contains criteria/standards for radiation therapy services. They are as follows:

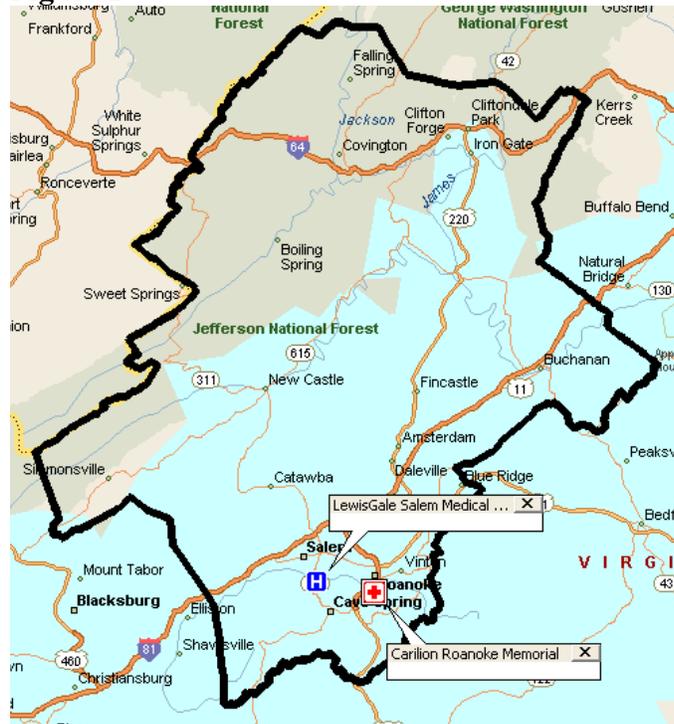
**Part III
Radiation Therapy Services
Article 1
Criteria and Standards for Radiation Therapy Services**

12VAC5-230-280. Travel time.

Radiation therapy services should be available within 60 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** shows the boundary of PD 5. The white “H” symbol with the blue background marks the locations of the only other provider of LINAC services in PD 5. The red “cross” symbol with the white background marks the location of the proposed project. The blue shading illustrates the area that is within a 60-minute driving time of the existing LINAC providers in PD 5. Based on the shaded area in **Figure 1**, it is reasonable to conclude that 95% of the population of PD 5 is within 60 minutes driving-time one-way under normal traffic conditions of LINAC services. The locations that are not within the shaded area include sections of Alleghany and Craig counties which are largely rural with small populations or are within the boundaries of the George Washington & Jefferson National Forest.

Figure 1



Source: Microsoft Streets & Trips

12VAC5-230-290. Need for new service.

A. No new radiation therapy service should be approved unless:

- 1. Existing radiation therapy machines located in the health planning district performed an average of 8,000 procedures per existing and approved radiation therapy machine in the relevant reporting period; and**
- 2. The new service will perform at least 5,000 procedures by the second year of operation without significantly reducing the utilization of existing providers in the health planning district.**

B. The number of radiation therapy machines needed in a health planning district will be determined as follows:

$$\frac{\text{Population} \times \text{Cancer Incidence Rate} \times 60\%}{320}$$

320

where:

- 1. The population is projected to be at least 150,000 people three years from the current year as reported in the most current projections of a demographic entity as determined by the commissioner;**
- 2. The cancer incidence rate as determined by data from the Statewide Cancer Registry;**
- 3. 60% is the estimated number of new cancer cases in a health planning district that are treatable with radiation therapy; and**

4. 320 is 100% utilization of a radiation therapy machine based upon an anticipated average of 25 procedures per case.

Not applicable. CMC is not proposing a new service, but rather the expansion of an existing service. Nevertheless, the number of radiation therapy machines is calculated as follows:

$(\text{PD 5 Population (2030)} \times \text{PD 5 Incidence Rate} \times 0.6) / 320$

$(277,947 \times 469.93^7 / 100,000) \times 0.6 / 320 = 2.45 (3)$

Current Inventory = 6

6 Current Inventory – 3 Needed = Surplus of 3

Based on the SMFP methodology for determining need for LINAC in the planning district, there is a need for 3 LINACs in PD 5 through 2030. As there are 6 COPN approved linear accelerators in PD 5, there is a **surplus of three LINACs**.

C. Proposals for new radiation therapy services located less than 60 minutes driving time one way, under normal conditions, from any site that radiation therapy services are available shall demonstrate that the proposed new services will perform an average of 4,500 procedures annually by the second year of operation, without significantly reducing the utilization of existing services in the health planning district.

Not applicable. The applicant is not proposing to add a new radiation therapy service but instead seeks to expand an existing service.

12VAC5-230-300. Expansion of service.

Proposals to expand radiation therapy services should be approved only when all existing radiation therapy services operated by the applicant in the health planning district have performed an average of 8,000 procedures for the relevant reporting period and the proposed expansion would not significantly reduce the utilization of existing providers.

CMC operates three of the six LINACs in PD 5 (**Table 7**). According to VHI data, in 2024 only one of the three LINACs operated by CMC did not perform an average of 8,000 procedures, while the other two well exceeded this threshold. Specifically, the two LINACs without SRS/SRT capability at CMC performed an average of 11,498 procedures per unit and the one LINAC with SRS/SRT capability at CMC only performed 758 procedures. The combined average for all three of CMC's LINACs, however, was 7,944 procedures per unit. While the combined average does not quite equal the 8,000 procedures, it is close enough to demonstrate that there is a need for additional capacity, particularly for conventional LINAC radiation therapy.

⁷ Source: www.statecancerprofiles.cancer.gov

The proposed project would not impact the volumes of LewisGale Medical Center, the only other LINAC service provider in PD 5, as it only did a total of 5,094 procedures (21.23% of the threshold) between its three units in 2024.

Table 7: PD 5 Linear Accelerator Inventory and Utilization

<i>Without SRS/SRT Capability</i>					
Facility	Units	Inpatient Treatment Visits	Outpatient Treatment Visits	Total Visits	Utilization
Carilion Roanoke Memorial Hospital	2	483	17,589	18,072	112.95%
LewisGale Medical Center	2	0	1	1	0.01%
Total	4	483	17,590	18,073	56.48%
<i>With SRS/SRT Capability</i>					
Facility	Units	Inpatient Treatment Visits	Outpatient Treatment Visits	Total Visits	Utilization
Carilion Roanoke Memorial Hospital	1	18	818	836	5.23%
LewisGale Medical Center	1	139	4,954	5,093	31.83%
Total	2	157	5,772	5,929	37.06%
<i>Combined non-SRS/SRT and with SRS/SRT</i>					
Facility	Units	Inpatient Treatment Visits	Outpatient Treatment Visits	Total Visits	Utilization
Carilion Roanoke Memorial Hospital	3	792	23,040	23,832	99.30%
LewisGale Medical Center	3	139	4,955	5,094	21.23%
Total	6	931	27,995	28,926	60.26%

Source: VHI, 2024

12VAC5-230-310. Statewide Cancer Registry.

Facilities with radiation therapy services shall participate in the Statewide Cancer Registry as required by Article 9 (§ 32.1-70 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia

The applicant asserts that CMC will continue to participate in the Statewide Cancer Registry consistent with Article 9 (§ 32.1-70 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia.

12VAC5-230-320. Staffing.

Radiation therapy services should be under the direction or supervision of one or more qualified physicians designated or authorized by the Nuclear Regulatory Commission or the Division of Radiologic Health of the Virginia Department of Health, as applicable.

The applicant has provided assurances that their radiation therapy services will continue to be under the direction or supervision of one or more qualified physicians.

Part I
Definitions and General Information

12VAC5-230-80. When Institutional Expansion is Needed.

- A. Notwithstanding any other provisions of this chapter, the commissioner may grant approval for the expansion of services at an existing medical care facility in a health planning district with an excess supply of such services when the proposed expansion can be justified on the basis of a facility's need having exceeded its current service capacity to provide such service or on the geographic remoteness of the facility.**
- B. If a facility with an institutional need to expand is part of a health system, the underutilized services at other facilities within the health system should be reallocated, when appropriate, to the facility with the institutional need to expand before additional services are approved for the applicant. However, underutilized services located at a health system's geographically remote facility may be disregarded when determining institutional need for the proposed project.**
- C. This section is not applicable to nursing facilities pursuant to § 32.1-102.3:1 of the Code of Virginia.**
- D. Applicants shall not use this section to justify a need to establish new services.**

CMC proposes to add one LINAC (without SRS/SRT capability) resulting in a total complement of four LINACs. With a utilization rate of 99.30% in 2024, CMC has demonstrated that its current utilization constitutes institutional need for expansion. Further, the two non-SRS/SRT units that are exclusively used for conventional radiation therapy operated at 143.73% of the SMFP threshold for expansion in 2024. CMC is also the top provider of LINAC services in PD 5, completing 23,832 of the 28,926 (82%) of the total procedures in the planning district in 2024.

As mentioned previously, neither DCOPN nor the applicant finds shifting volumes from the non-SRS/SRT capable units to the highly specialized Cyberknife system that is exclusively used for SRS as a viable option.

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;**

DCOPN contends that approval of the proposed project will not introduce institutional competition because, as previously discussed, CMC is the primary provider of LINAC services in PD 5, completing 83% of all LINAC procedures in 2024. CMC also already has an established patient base that is unique from that of LewisGale.

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 mentioned, CMC operates three of the six LINACs in PD 5 (50%). In total, CMC's three scanners operated at 99.30% of the SMFP threshold for expansion, and LewisGale's three units operated at 21.23%.

DCOPN concludes that it is unlikely that approval of the project would significantly affect the utilization or efficiency of other existing or COPN approved providers of LINAC services in PD 5.

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

The Pro Forma Income Statement (**Table 6**) provided by the applicant projects net operating income of \$11,023,352 by the end of the first year of operation and net operating income of \$11,521,705 by the end of year two for the proposed project. The total capital and financing cost of the proposed project is \$3,782,869, of which approximately 92.9% represents equipment costs (**Table 2**). The proposed project will be funded through accumulated reserves of the applicant and therefore, there are no financing costs associated with the proposed project.

With regard to staffing, the applicant anticipates the need to hire four Full Time Equivalent (FTE) employees to staff the proposed project, one physicist, and three miscellaneous personnel.

Regarding recruiting staff, the applicant stated the following:

“Carilion Clinic has a robust talent acquisition team that uses its resources (including internal and external landing pages) to post jobs and recruit internal and external applicants to these positions”.

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 will not introduce new technology that would promote quality or cost effectiveness in the delivery of inpatient acute care, as the applicant is not upgrading to a machine that is SRS/SRT capable. The proposed project also does increase the potential for provision of services on an outpatient basis. DCOPN did not identify any other factors that have not been discussed elsewhere in this staff analysis report to bring to the attention of the Commissioner.

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.
 - (ii) Any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care for citizens of the Commonwealth, including indigent or underserved populations.

With regard to this consideration, the applicant provided the following information:

Medical school affiliations include the Virginia Tech Carilion School of Medicine (VTC), 30 accredited resident and fellow training programs, and the Via College of Osteopathic Medicine (VCOM). Additionally, Radford University Carilion educates and trains students in 20 health science programs from associates to doctoral levels including nursing and other ancillary health services.

DCOPN Findings and Conclusions

DCOPN finds that Carilion Medical Center's (CMC) proposed project add one linear accelerator (LINAC) at Carilion Medical Center, for a total complement of four linear accelerators is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. According to 2024 VHI data, the latest year for which such data is available, CMC's three existing LINACs operated at 99.30% of the threshold for expansion. Further, the two non-SRS/SRT scanners, the same type CMC is trying to add with this project, operated at 143.73% of the SMFP threshold, demonstrating a clear institutional need for an additional LINAC that can perform conventional radiation therapy. CMC is also the primary provider of radiation therapy services in PD, performing 82% of all LINAC procedures in PD 5 in 2024.

There is no known opposition to the project, the cost is reasonable, and the project is unlikely to affect the utilization of other area providers. The proposal is wholly feasible in the immediate and long-term.

Additionally, DCOPN is not aware of a reasonable alternative to the project that would be less costly, more efficient, or more effective at meeting the needs of the PD 5 population. The proposal is more beneficial than the status quo.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **conditional approval** of Carilion Medical Center d/b/a Carilion Roanoke Memorial Hospital's COPN Request No. VA-8863 to add one additional linear accelerator at Carilion Medical Center, for a total complement of four linear accelerators, 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 of the proposed project are reasonable, and it appears to be wholly viable in the immediate and long term.
3. The applicant has demonstrated an institutional need to expand.
4. The project is not likely to have a negative impact on other providers in planning district 5.
5. The project is more favorable than maintaining the status quo.
6. There is no known opposition to the proposed project.

DCOPN's recommendation is contingent upon Chippenham & Johnston-Willis Hospitals, Inc.'s agreement to the following charity conditions:

Carilion Medical Center d/b/a Carilion Roanoke Memorial Hospital will provide radiation therapy to all persons in need of these services, 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 0.5% of Carilion Medical Center d/b/a Carilion Roanoke Memorial Hospital's gross patient revenue derived from radiation therapy services. 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 Medical Center d/b/a 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 Medical Center d/b/a Carilion Roanoke Memorial Hospital will provide radiation therapy 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 Medical Center d/b/a 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.