VIRGINIA DEPARTMENT OF HEALTH
Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis Report

March 21, 2025

COPN Request No. VA-8801
Carilion Medical Center d/b/a Carilion Roanoke Memorial Hospital
Roanoke, Virginia
Introduce Proton Beam Therapy and add 1 CT scanner for radiation therapy simulation

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

Proton therapy uses the positively charged particles in an atom (protons) that release their energy within the target: the tumor. There is lower entrance radiation and virtually none travels beyond the tumor. Because proton beams can be much more finely controlled, specialists can safely deliver higher doses of radiation to tumors when needed.[1]

Proton therapy is beneficial in the treatment of many kinds of tumors, including brain, breast, esophageal, eye, gastrointestinal, gynecological, head and neck, liver, lung, lymphoma, prostate, soft tissue, spine, and many pediatric cancers.[2]

The benefits of proton therapy include:

- Ability to deliver higher therapeutic doses of radiation to tumors;
- Lower radiation exposure to normal tissue, reducing short- and long-term side effects, including development of new cancers; and

[1] Mayo Foundation for Medical Education and Research. (June 22, 2023). *Proton Beam Therapy Program*. Mayo Clinic. (accessed March 5, 2025) https://www.mayoclinic.org/departments-centers/proton-beam-therapy-program/sections/overview/ovc-20185491
[2] Id

- A treatment alternative for people with cancer recurrences who have undergone previous radiation therapy procedures[3]

Certificate of Public Need (COPN) authorization of a proton beam therapy system at CRMH would create the third such cancer treatment center in the Commonwealth of Virginia. The first proton beam therapy system was authorized at the Hampton University Proton Therapy Institute (HUPTI) in Hampton, Virginia, (PD 21, HPR V) in 2005 and the second was authorized at Inova Fairfax Hospital in Falls Church, Virginia (PD 8, HPR II) in 2017. There are a total of 52 proton beam therapy centers in the United States – either in operation (46) or under construction or development (6).[4]

With regard to traditional radiation therapy, according to Virginia Health Information (VHI) data and Division of Certificate of Public Need (DCOPN) records, there are six COPN authorized linear accelerators in PD 5 (**Table 1**). In 2023, these linear accelerators operated at a utilization rate of 50.2%. Additionally, DCOPN records show that there is currently one COPN authorized computed tomography (CT) simulator in PD 5 at LewisGale Medical Center.

Table 1. PD 5 COPN Authorized Linear Accelerator Units and 2023 Utilization

Facility	Units	Inpatient Treatment Visits	Outpatient Treatment Visits	Total Visits	Utilization
Carilion Roanoke Memorial Hospital	3	397	18,639	19,036	79.3%
LewisGale Medical Center	3	143	4,916	5,059	21.1%
Total/Average	**6**	**540**	**23,555**	**24,095**	**50.2%**

Source: DCOPN records and VHI (2023)

Proposed Project

The applicant proposes to introduce one proton beam accelerator and one associated CT simulator at CRMH located at 1906 Belleview Avenue SE, Roanoke, Virginia. The CT simulator will only be used for "precise image guided treatment and planning" and will not be used for diagnostic purposes. The applicant explains that CRMH intends to centralize all cancer treatment services, including radiation therapy services, in a newly constructed building dedicated to cancer services located adjacent to Carilion Riverside 3 on the CMC campus. The new building will be called the Carilion Taubman Cancer Center ("CTCC"). Currently, CRMH's radiation therapy services consist of three linear accelerators. The applicant plans to acquire the MEVION S250i proton therapy system, a compact system designed for precise and efficient treatment delivery, and a dedicated and integrated CT simulator, that will be used solely for proton therapy services, and not for diagnostic imaging.

The total capital costs of the proposed project are $47,042,540, of which approximately 44% represents direct construction costs (**Table 2**). The proposed project will be funded through the

[3] Id.
[4] *Find a Proton Therapy Center*. National Association for Proton Therapy. (accessed March 5, 2025) https://proton-therapy.org/findacenter/

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	$20,592,540
Equipment Not Included in Construction Contract	$25,450,000
Architectural and Engineering Fees	$1,000,000
Total	**$47,042,540**

Source: COPN Request No. VA-8801

Construction for the proposed project is expected to begin on January 15, 2026, and to be completed on November 30, 2027. The applicant anticipates an opening date in December 2027.

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the "[t]he addition by an existing medical care facility described in subsection A of any new medical equipment for the provision of…radiation therapy…." and "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 CMC campus is located at 1906 Belleview Avenue SE, Roanoke, Virginia. off Interstate 581. According to the applicant, "[t]he 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." Additionally, the CRMH campus is accessible by Valley Metro, the public transportation provider for the Roanoke Valley and the SmartWay bus, which links the Roanoke Valley and the New River Valley. Furthermore, the Star Line-Trolley Service connects downtown Roanoke, where the major stops for Amtrak and Valley Metro are to the CMC campus. The applicant also provided the following information:

> 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, two miles from CRMH. From the Amtrak station, the

Valley Metro Bus Station is a two-minute walk for bus or trolley service to the CMC campus.

The population of PD 5 is projected to be 284,571 by 2030 and it is projected to grow by 1% during the 2020 to 2030 decade, a significantly lower rate of growth than the projected growth for Virginia which is 5.8% during the same period (**Table 3**). The population over age 65 is projected to grow faster than the overall population, about 45%, in PD 5 during the same decade, compared with 26.3% across Virginia (**Table 3**).

Table 3. Population by Locality, PD 5

Locality	2020 Population	2030 Projected Population	Projected Growth 2020-2030	Percent Growth 2020-2030	65+ 2020 Population	Projected 65+ 2030 Population	Projected Growth 65+	Percent Growth 65+
Alleghany	15,223	13,993	(1,230)	-8.08%	3,933	5,271	1,338	34.02%
Botetourt	33,596	33,556	(40)	-0.12%	7,882	11,786	3,904	49.53%
Craig	4,892	4,528	(364)	-7.44%	1,124	1,652	528	46.95%
Roanoke County	96,929	100,027	3,098	3.20%	21,449	31,009	9,560	44.57%
Covington city	5,737	5,434	(303)	-5.28%	1,201	1,688	487	40.54%
Roanoke city	100,011	101,514	1,503	1.50%	17,899	26,059	8,160	45.59%
Salem city	25,346	25,519	173	0.68%	5,328	7,653	2,325	43.64%
PD 5	**281,734**	**284,571**	**2,837**	**1.01%**	**58,816**	**85,118**	**26,302**	**44.72%**
Virginia	**8,631,393**	**9,129,002**	**497,609**	**5.8%**	**1,395,291**	**1,762,641**	**367,350**	**26.3%**

Source: United States Census Bureau at https://data.census.gov/ and Weldon Cooper Center for Public Service, August 2023.

DCOPN notes that according to the most recent U.S. Census data, the City of Roanoke has a poverty rate of 18.4% - much higher than the statewide average (10.2%) and more than every other locality within PD 5 (**Table 4)**.

Table 4. Statewide and PD 5 Poverty Rates

Locality	Poverty Rate
Virginia	10.2%
Alleghany County	13.9%
Botetourt County	6.3%
Craig County	12.3%
Roanoke County	7.2%
Covington City	17.7%
Roanoke City	18.4%
Salem City	10.4%
PD 5	**12.4%**

Source: U.S. Census Small Area Income and Poverty Estimates Data - 2023 (Census.gov)

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 by HPR III facilities was 0.6% of all reported total gross patient revenues (**Table 5**). Pursuant to § 32.1-102.4B of the Code of Virginia DCOPN must now place a charity care condition on every applicant seeking a COPN. Accordingly, should the Commissioner approve the proposed

project, DCOPN recommends a charity care condition of no less than the 0.6% HPR III average, in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

Table 5. HPR III Charity Care Contributions

2022 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	**Gross Patient Revenues**	**Adjusted Charity Care Contribution**	**% of Gross Patient Revenue:**
Rehabilitation Hospital of Bristol, LLC	$17,981,903	$504,759	2.8%
Centra Specialty Hospital	$48,716,727	$1,120,485	2.3%
Carilion Franklin Memorial Hospital	$216,535,912	$4,076,850	1.9%
Carilion Tazewell Community Hospital	$84,561,982	$1,031,972	1.2%
Carilion Giles Memorial Hospital	$182,762,966	$2,056,398	1.1%
Carilion Medical Center	$4,626,293,362	$48,146,682	1.0%
Carilion New River Valley Medical Center	$908,326,659	$8,974,962	1.0%
LewisGale Hospital-Montgomery	$945,286,546	$6,043,431	0.6%
LewisGale Hospital - Alleghany	$259,238,606	$1,552,971	0.6%
LewisGale Hospital Pulaski	$465,079,395	$2,565,485	0.6%
Lewis-Gale Medical Center	$2,945,087,457	$16,161,621	0.5%
Centra Health	$3,023,784,179	$10,182,695	0.3%
Smyth County Community Hospital	$214,723,312	$630,654	0.3%
Bedford Memorial Hospital	$175,626,005	$474,228	0.3%
Norton Community Hospital	$291,775,554	$767,018	0.3%
Russell County Medical Center	$135,556,168	$330,439	0.2%
Dickenson Community Hospital	$28,125,420	$68,308	0.2%
Johnston Memorial Hospital	$826,084,738	$1,856,940	0.2%
Wellmont Lonesome Pine Mountain View Hospital	$779,003,003	$1,458,898	0.2%
Lee County Community Hospital	$35,910,227	$49,714	0.1%
Buchanan General Hospital	$116,385,318	$140,702	0.1%
DLP Twin County Regional Healthcare	$255,330,355	$293,349	0.1%
Sovah Health-Martinsville	$677,045,264	$349,080	0.1%
Clinch Valley Medical Center	$656,673,348	$293,630	0.0%
Sovah Health-Danville	$932,808,724	$86,078	0.0%
Wythe County Community Hospital	$292,907,698	$18,259	0.0%
Ridgeview Pavilion (Bristol Region)	$7,807,715	$ -	0.0%
Total Facilities Reporting			27
Median			**0.3%**
Total $ & Mean %	$19,149,418,543	$109,235,608	**0.6%**

Source: VHI (2022)

As previously discussed, The first proton beam therapy system was authorized at the HUPTI in Hampton, Virginia, (PD 21, HPR V) in 2005 and the second was authorized at Inova Fairfax Hospital in Falls Church, Virginia (PD 8, HPR II) in 2017. The HUPTI proton beam therapy program is 262 miles and approximately four hours from CRMH and the Inova Fairfax Hospital proton beam therapy is 233 miles and three and ½ hours from CRMH.

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 11 letters of support for the proposed project, which addressed:

- CRMH will be the sole provider of proton beam therapy in the area, reaching far beyond Planning District 5 to the most southwestern regions in Virginia.

- There is significant public and philanthropic support from the community.

- The benefits [proton beam therapy] can provide to pediatric patients over the currently available technologies cannot be overstated. This is most important in the treatment of pediatric brain tumors, which are the most common solid tumor and the second most common cancer overall in children and adolescents.

- [Proton beam therapy] offers an innovative, effective and safer alternative in a variety of cancer treatment plans. It is also underutilized in SW Virginia quite simply because the current proton centers are too far from [SW Virginia].

- Proton beam therapy represents a state-of-the-art treatment option for patients with benign and malignant brain tumors, particularly those that are inoperable. The key benefit of proton beam therapy is its ability to deliver high doses of radiation precisely to tumors while minimizing damage to surrounding critical brain structures. This allows for effective radiation treatment where other forms of radiation therapy fall short, providing a safer and more targeted approach to care.

- CRMH's patients want access to proton beam therapy, and they want to remain in southwestern Virginia for their care whenever possible, especially when faced with a dreaded diagnosis of cancer, when support and proximity from their family, friends, and faith community are more important than ever.

- [Proton beam therapy] addition will directly benefit the neurosurgical oncologic patients, as well as many translational research effect that will benefit the population of Southwest Virginia.

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-8801 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;

As previously discussed, there are only two current providers of proton beam therapy in the Commonwealth, the HUPTI in Hampton, Virginia, (PD 21, HPR V) and Inova Fairfax Hospital in Falls Church, Virginia (PD 8, HPR II). The HUPTI proton beam therapy program is 262 miles and approximately four hours from CRMH and the Inova Fairfax Hospital proton beam therapy is 233 miles and three and ½ hours from CRMH. This distance prohibits many of the patients in CRMH's service area from receiving proton beam therapy. As explained in the application:

> [T]here are only two proton beam therapy providers in Virginia, Hampton University Proton Cancer Institute and Inova Fairfax. The excessive distance to these facilities currently makes proton beam therapy an impractical and costly treatment option for most residents of Southwest Virginia. As a result, most Southwest Virginia residents who might benefit from proton beam therapy are required to choose less effective and/or high-risk treatment alternatives.

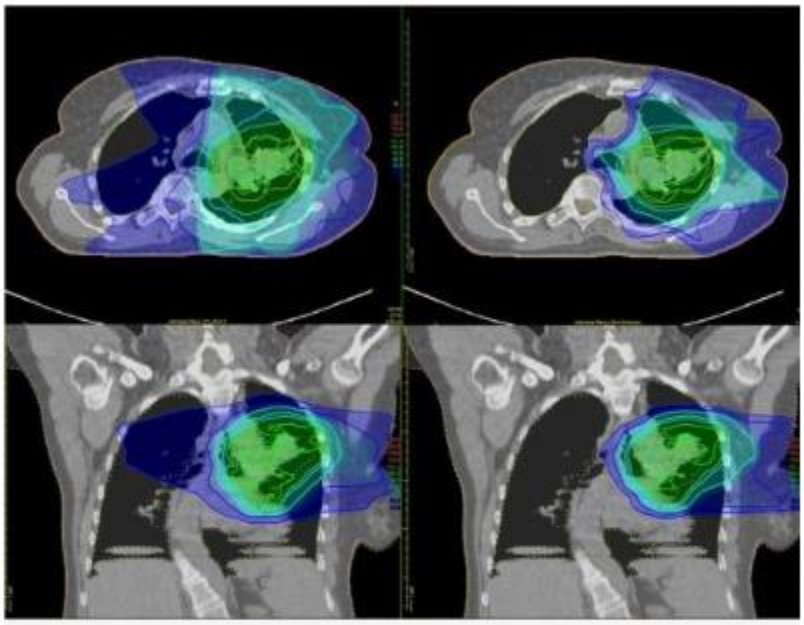
As shown in **Table 1** above, the six linear accelerators in PD 5 operated at 50.2% utilization in 2023. More specifically, the three linear accelerators at CRMH operated at 79.3% utilization in 2023. Because the linear accelerators in PD 5 have available capacity, it may appear that the status quo is a reasonable alternative to the proposed project. However, proton beam therapy differs from and offers several advantages over traditional radiation therapy, including the distance that the radiation travels in the body, as explained below:

> More importantly, protons only travel a certain distance into the body before they stop, and they deliver the highest dose of radiation at the end of their pathway. This burst of energy can appear on a graph as what is called the Bragg peak. Radiation oncologists plan proton therapy treatments so the maximum dose hits the tumor cells. In this way, proton therapy reduces radiation exposure and potential damage to healthy tissue, especially in sensitive areas such as the brain, eyes, spinal cord, heart, reproductive organs, major blood vessels and nerves.
>
> In regular radiation therapy, such as photon therapy or gamma knife treatments, the beam of high-energy gamma rays or X-rays goes into the body, through the tumor and out the other side. Photons release energy along the entire path they travel, which means they radiate healthy tissues beyond the tumor. It is estimated that 30% to 40% of the photon dose passes through the tumor. This "exit dose" of radiation can damage the DNA of healthy cells. Proton therapy generates virtually no exit dose.[5]

[5] Johns Hopkins Medicine. *Proton therapy*. (accessed March 14, 2025) https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/proton-therapy

Figure 1 below illustrates the radiation of healthy tissue beyond the scope of the tumor for both traditional radiation therapy and proton beam therapy.

Figure 1



Traditional radiation therapy (top and bottom left) delivers radiation to the tumor and to healthy tissues around the tumor. With proton therapy (top and bottom right), the majority of the radiation is delivered to the tumor.

Source: https://www.cancer.gov/news-events/cancer-currents-blog/2020/proton-therapy-safety-versus-traditional radiation#:~:text=Traditional%20radiation%20delivers%20x%2Drays,to%20damage%20nearby%20healthy%20tissues.

Finally, the requested CT simulator will be exclusively dedicated to radiation therapy planning in conjunction with the proton beam therapy, and thus, the lengthy radiation therapy planning procedures required will have no impact on the hospital's existing CT scanners. For these reasons, DCOPN concludes that the proposed project is more advantageous the status quo.

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

Currently there is no organization in HPR 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 $47,042,540, of which approximately 44% represents direct construction costs. As previously discussed, authorization of a proton beam therapy system at CRMH would create the third such cancer treatment center in the Commonwealth of Virginia. The first proton beam therapy system was authorized at the HUPTI in Hampton, Virginia and cost $148,934,571 and the second was authorized at Inova Fairfax Hospital in Falls Church, Virginia and cost $93,239,505. DCOPN observes that the cost of establishing a proton beam therapy service appears to be going down but is still quite expensive. However, the proposed project will be funded through the accumulated reserves of the applicant. Therefore, there are no financing costs associated with the proposed project.

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

- The centralization of all cancer treatment services in the CTCC at CRMH will provide our expansive patient population with a new and unique one-stop opportunity for the provision of cancer treatment services.

- The introduction and establishment of proton beam therapy services will be an important component of comprehensive cancer care that will be provided to cancer patients throughout an expanding region.

- This [project] represents a significant advancement in radiation therapy, offering a highly precise way to target tumors while minimizing damage to surrounding healthy tissue. This is particularly important for patients with tumors located near vital organs or sensitive areas, where minimizing radiation exposure to healthy tissue is essential.

- Another key benefit is the risk reduction in pediatric cancers where children often suffer long-lasting side effects from the more toxic cancer treatments available.

- [Proton beam therapy] can also be beneficial for patients who need further therapy in an area previously treated with traditional radiation or patients who are unable to receive any more traditional radiation due to toxicity risks.

- Currently, there are only two proton beam therapy providers in the Commonwealth of Virginia. The Hampton University Proton Cancer Institute is a three hour and forty-five-minute drive from CRMH. Inova Fairfax is a three hour and twenty-minute drive from CRMH. These driving times are even longer for residents living to the southwest of Roanoke. The introduction of proton beam therapy at CRMH's new CTCC will improve geographic access to a highly specialized cancer service for cancer patients throughout Southwestern Virginia.

- The excessive distance to these facilities currently makes proton beam therapy an impractical and costly treatment option for most residents of Southwest Virginia. As a result, most

Southwest Virginia residents who might benefit from proton beam therapy are required to choose less effective and/or high-risk treatment alternatives.

(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, DCOPN recommends a charity care condition of no less than the 0.6% HPR III average, 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	$21,359,409	$27,366,743
Contractual Allowances	($14,842,653)	($19,017,150)
Charity Care	($108,933)	($139,570)
Net Patient Revenue	$6,407,823	$8,210,023
Total Expenses	$5,893,970	$7,916,316
Net Operating Income	$513,852	$293,707

Source: COPN Request No. VA-8801

(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 the establishment or expansion of CT services. They are as follows:

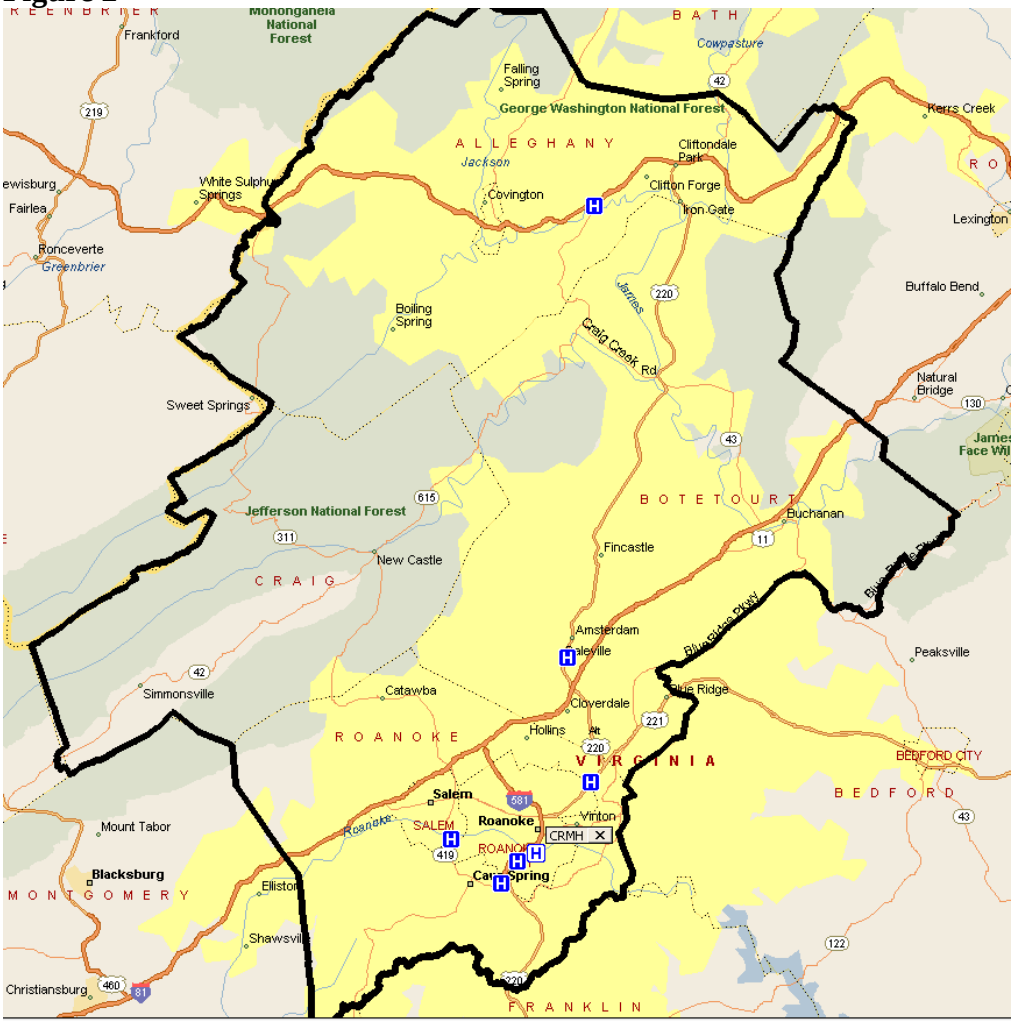
Part II
Diagnostic Imaging Services
Article 1
Criteria and Standards for Computed Tomography

12VAC5-230-90. Travel time.

CT services should be available within 30 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the commissioner.

The heavy black line in **Figure 2** is the boundary of PD 5. The blue "H" symbols mark the locations of existing CT providers in PD 5. The white "H" symbol marks the location of the proposed project. The yellow shaded area includes all locations that are within 30 minutes driving time one-way under normal conditions of CT services in PD 5. DCOPN notes that the proposed project does not include diagnostic CT services and will not improve access to diagnostic CT services.

Figure 2



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 not significantly reduce the utilization of existing providers in the health planning district. The utilization of existing scanners operated by a hospital and 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.

Not applicable. The CT simulator will only be used for "precise image guided treatment and planning" and will not be used for diagnostic purposes. The proposed CT simulator is, therefore, exempt from the utilization criteria of this section.

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.

Not applicable. The proposed CT simulator will be used solely for simulation with proton beam therapy, and is, therefore, exempt from the utilization criteria of this section.

12VAC5-230-110. Expansion of fixed site service.

Proposals to expand an existing medical care facility's CT service through the addition of a 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.

The applicant is not seeking to expand its fixed site diagnostic CT services; rather it is seeking the addition of a fixed CT simulator to be used solely for simulation with proton beam therapy.

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 CT scanner and that the proposed conversion will not significantly reduce the utilization of existing CT providers in the health planning district.

Not applicable. The applicant is not seeking to add or expand mobile CT services or to convert authorized mobile CT scanners to fixed site scanners.

12VAC5-230-130. Staffing.
CT services should be under the direction or supervision of one or more qualified physicians.

The applicant provided assurances that CT simulation services will be under the direction or supervision of one or more qualified physicians.

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

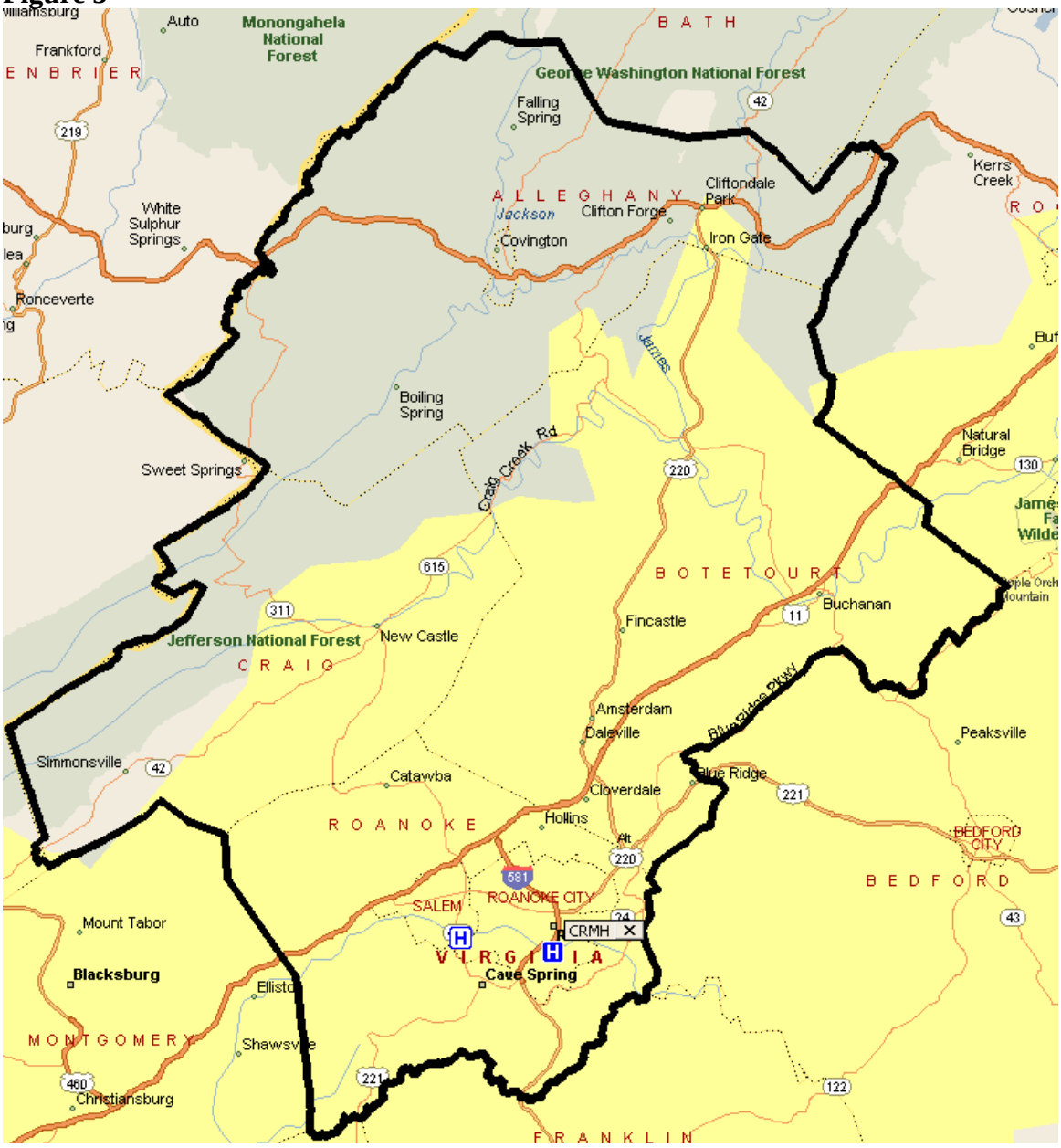
Part III
Radiation Therapy Services
Article 1
Criteria and Standards for Radiation Therapy Services

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 3** shows the boundary of PD 5. The white "H" symbols mark the locations of existing radiation therapy providers in PD 5. The blue "H" symbol marks the location of the proposed project. The yellow shading illustrates the area that is within a 60-minute driving time of the existing radiation therapy providers in PD 5. Based on the shaded area in **Figure 3**, it is unclear if 95% of the population of PD 5 is within 60 minutes driving-time one-way under normal traffic conditions of radiation therapy services. However, as previously discussed, proton beam therapy is not traditional radiation therapy, and therefore, approval of the proposed project will not affect access to traditional radiation therapy services.

Figure 3


Auto
Monongahela National Forest
Frankford
BATH
George Washington National Forest
Falling Spring
42
219
Kerrs Creek
Cliftondale Park
ALLEGHANY
Jackson
Clifton Forge
White Sulphur Springs
Covington
Iron Gate
Ronceverte
James
Boiling Spring
Craig Creek Rd
Natural Bridge
130
220
Sweet Springs
615
BOTETOURT
311
Buchanan
11
Fincastle
Jefferson National Forest
New Castle
CRAIG
Amsterdam
Daleville
Blue Ridge Pkwy
Peaksville
Simmonsville
42
Catawba
Cloverdale
Blue Ridge
221
ROANOKE
Hollins
BEDFORD CITY
581
220
ROANOKE CITY
SALEM
BEDFORD
Mount Tabor
CRMH
Blacksburg
Cave Spring
VIRGINIA
MONTGOMERY
Shawsville
460
Christiansburg
221
122
FRANKLIN

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.

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

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

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

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.

Table 7 below shows the projected population and new cancer cases requiring radiation therapy in PD 5. Based on the SMFP methodology for determining need for linear accelerators in the planning district, there is a need for three linear accelerators in PD 5 through 2028. As there are six COPN approved linear accelerators in PD 5, there is an existing surplus of three linear accelerator in PD 5.

Table 7. Number of radiation therapy machines needed in PD 5

Locality	PD 5 2028 Population	Cancer Incidence Rate (Per 100,000)	2028 Projected Cancer Cases	New Cancer Cases Requiring RT	Linear Accelerators Needed
PD 5	281,734	471.7	1,340	804	3

Source: Weldon-Cooper Data, updated August 2023 and DCOPN (interpolations) and National Cancer Institute Incidence Rates Table (Latest Five-Year Average)

However, as previously discussed, proton beam therapy is not traditional radiation therapy, and therefore, approval of the proposed project will not affect the existing surplus of linear accelerators in PD 5.

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.

As previously discussed, proton beam therapy is not traditional radiation therapy, and therefore, approval of the proposed project will not affect the existing surplus of linear accelerators in PD 5.

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.

As shown in **Table 1** above, according to VHI data and DCOPN records, there are six COPN authorized linear accelerators in PD 5. In 2023, these linear accelerators operated at a utilization rate of 50.2%. However, as previously discussed, proton beam therapy is not traditional radiation therapy, and therefore, approval of the proposed project is unlikely to affect the utilization of linear accelerators in PD 5.

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 CRMH will continue to participate in the Virginia Tumor Registry.

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.

With regard to this requirement, the applicant explains, "[r]adiation therapy services at CRMH are under the direction and supervision of board-certified oncologists who are authorized by the Nuclear Regulatory Commission or the Division of Radiologic Health of the Virginia Department of Health."

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;

As previously discussed, authorization of a proton beam therapy system at CRMH would create the third such cancer treatment center in the Commonwealth of Virginia. The first proton beam therapy system was authorized at the HUPTI in Hampton, Virginia, (PD 21, HPR V) in 2005 and the second was authorized at Inova Fairfax Hospital in Falls Church, Virginia (PD 8, HPR II) in 2017. There are a total of 52 proton beam therapy centers in the United States – either in operation (46) or under construction or development (6).[6] The HUPTI proton beam therapy program is 262 miles and approximately four hours from CRMH and the Inova Fairfax Hospital proton beam therapy is 233 miles and three and ½ hours from CRMH. Therefore, approval of the proposed project would introduce a new service not currently available to residents of HPR III without lengthy travel times. The availability of a more precise treatment with fewer side effects could introduce beneficial competition by attracting patients who would otherwise receive traditional radiation therapy.

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 shown in **Table 1** above, according to VHI data and DCOPN records, there are six COPN authorized linear accelerators in PD 5. In 2023, these linear accelerators operated at a utilization rate of 50.2%. However, as previously discussed, proton beam therapy is not traditional radiation therapy, and therefore, approval of the proposed project is unlikely to affect the utilization of linear accelerators 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 $513,852 by the end of the first year of operation and net operating income of $293,707 by the end of year two for the proposed project. The total capital and financing cost of the proposed project is $47,042,540, of which approximately 44% represents direct construction costs (**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.

With regard to staffing, the applicant anticipates the need to hire seven Full Time Equivalent (FTE) employees to staff the proposed project – four radiation therapists, one physicist and two dosimetrists. With regard to recruitment, the applicant says, "Carilion Clinic has a robust talent acquisition team that uses its resources (including internal and external landing pages) to post jobs

[6] *Find a Proton Therapy Center*. National Association for Proton Therapy. (accessed March 5, 2025) https://proton-therapy.org/findacenter/

and recruit internal and external applicants to these positions. As needed, outside recruiting agencies are used for key positions that may be difficult to find or recruit."

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

As previously discussed, proton beam therapy differs from and offers several advantages over traditional radiation therapy, including the distance that the radiation travels in the body, as explained below:

> More importantly, protons only travel a certain distance into the body before they stop, and they deliver the highest dose of radiation at the end of their pathway. This burst of energy can appear on a graph as what is called the Bragg peak. Radiation oncologists plan proton therapy treatments so the maximum dose hits the tumor cells. In this way, proton therapy reduces radiation exposure and potential damage to healthy tissue, especially in sensitive areas such as the brain, eyes, spinal cord, heart, reproductive organs, major blood vessels and nerves.
>
> In regular radiation therapy, such as photon therapy or gamma knife treatments, the beam of high-energy gamma rays or X-rays goes into the body, through the tumor and out the other side. Photons release energy along the entire path they travel, which means they radiate healthy tissues beyond the tumor. It is estimated that 30% to 40% of the photon dose passes through the tumor. This "exit dose" of radiation can damage the DNA of healthy cells. Proton therapy generates virtually no exit dose.[7]

Additionally, CT simulation has become the standard of care for planning radiation therapy treatment.

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.

[7] Johns Hopkins Medicine. *Proton therapy*. (accessed March 14, 2025) https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/proton-therapy

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 t0
(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), 28 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 d/b/a Carilion Roanoke Memorial Hospital's COPN Request No. VA-8801 to introduce proton beam therapy and add one CT scanner for radiation therapy simulation is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia.

As previously discussed, there are only two current providers of proton beam therapy in the Commonwealth, the HUPTI in Hampton, Virginia, (PD 21, HPR V) and Inova Fairfax Hospital in Falls Church, Virginia (PD 8, HPR II). The HUPTI proton beam therapy program is 262 miles and approximately four hours from CRMH and the Inova Fairfax Hospital proton beam therapy is 233 miles and three and ½ hours from CRMH. This distance prohibits many of the patients in CRMH's service area from receiving proton beam therapy and bringing the proton beam therapy service to HPR III will bring a unique service to residents of the area and beyond. Furthermore, As shown in **Table 1** above, the six linear accelerators in PD 5 operated at 50.2% utilization in 2023. More specifically, the three linear accelerators at CRMH operated at 79.3% utilization in 2023. Because the linear accelerators in PD 5 have available capacity, it may appear that the status quo is a reasonable alternative to the proposed project. However, as previously discussed, proton beam therapy differs from and offers several advantages over traditional radiation therapy, including the distance that the radiation travels in the body. For the reasons discussed, the status quo is not a preferable alternative to the proposed project.

Moreover, DCOPN finds that the total capital costs of the proposed project, while extremely high, appear reasonable when compared to the development costs of other proton beam therapy services. The proposed project will be funded through accumulated reserves of the applicant. Therefore, there are no financing costs associated with the proposed project. Furthermore, DCOPN finds that the project appears to be economically feasible both in the immediate and long-term.

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-8801 to introduce proton beam therapy and add one CT scanner for radiation therapy simulation, 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. Although extremely high, the capital costs appear reasonable when compared to the development costs of other proton beam therapy services.

3. The proposed project appears economically viable in the long-term.

4. The project is more favorable than maintaining the status quo.

5. The proposed proton beam therapy service is an advanced form of radiation therapy. As a regional referral, tertiary and teaching hospital, CRMH is the appropriate site for this type of cancer treatment in HPR III.

Recommended Condition
Carilion Medical Center d/b/a Carilion Roanoke Memorial Hospital will provide proton beam therapy and CT simulation services 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 0.6% of Carilion Medical Center d/b/a Carilion Roanoke Memorial Hospital's total patient services revenue derived from proton beam therapy and CT simulation 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 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 proton beam therapy and CT simulation 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.