VIRGINIA DEPARTMENT OF HEALTH
Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis Report

March 21, 2022

COPN Request No. VA-8608
Richmond Radiation Oncology Center I LLC & Bon Secours-St. Mary's Hospital of Richmond LLC
Mechanicsville, Virginia
Establish a Specialized Center for Radiation Therapy Services with one Linear Accelerator with SRS/SRT and one CT Simulator

Applicant

Bon Secours – St. Mary's Hospital of Richmond LLC (BSSM) is a Virginia Limited Liability Company. The sole member of BSSM is Bon Secours – Richmond Health System d/b/a Bon Secours Virginia Health System (BSRVA). BSRVA is also the sole owner of Bon Secours – Virginia HealthSource, Inc. Bon Secours Richmond, LLC is the sole corporate member of BSRVA. Richmond Radiation Oncology Center I LLC (RROCI) is a Virginia Limited Liability Company. RROCI is a joint venture between Accelerad, LLC and Richmond Radiation Oncology Center, Inc. Accelerad, LLC is owned by the physicians of Virginia Urology. Bon Secours – Virginia HealthSource, Inc. is the sole shareholder of Richmond Radiation Oncology Center, Inc. The proposed project would be located in Mechanicsville, Virginia, Health Planning Region (HPR) IV, Planning District (PD) 15.

Background

BSSM is a 391-bed acute care facility that provides a comprehensive array of inpatient and outpatient tertiary services, including but not limited to cardiology, behavioral medicine services, surgery, orthopedics, neurosciences, oncology, women's services and pediatrics. BSRVA is designated as an Integrated Network Cancer Program. Integrated Network Cancer Programs are those "facilities belonging to an organization that owns a group of facilities that offer integrated and comprehensive cancer care services and is overseen by a centralized governance structure/board and CEO[1]. This designation would apply to the proposed specialized center for radiation therapy services should the project receive approval.

On May 31, 2007, Richmond Radiation Oncology Center, Inc. submitted an application for COPN Request No. VA-7461, which proposed to establish Bon Secours Cancer Center at Hanover in Hanover County by relocating one of the two linear accelerators from BSSM. This

[1] American College of Surgeons, https://www.facs.org/quality-programs/cancer/coc/accreditation/categories#incp

project's proposed location would have been located approximately 1.6 miles from the proposed location for Bell Creek. In January 2008, the Commissioner denied the proposed project finding, in part, that the project was not consistent with the SMFP and that the project would unnecessarily duplicate existing radiation therapy services.

On April 28, 2010, the Commissioner issued COPN No. VA-04255 to Richmond Radiation Oncology Center, Inc., Richmond Radiation Oncology Center I LLC & Bon Secours-St. Mary's Hospital of Richmond, Inc. to relocate and replace one linear accelerator from BSSM to Bon Secours St. Francis Medical Center. This approval was based, in part, on an institutional need at Bon Secours St. Francis Medical Center.

On April 26, 2013, the applicants filed a significant change to extend the timeframe of completion of the project authorized by COPN No. VA-04255 by two years to April 2015. The Commissioner approved this significant change on June 13, 2013. On October 27, 2014, the applicants filed a second significant change to change the location from Bon Secours St. Francis Medical Center to Bon Secours Memorial Regional Medical Center (BSMRM). BSMRM is located 0.7 miles from the location proposed in the denied COPN Request No. VA-7461 and 2.3 miles from the current proposed Bell Creek location. The Commissioner denied this second significant change on November 25, 2014. On April 29, 2015, an IFFC was held to reconsider the denial of the second significant change. On June 9, 2015, the Commissioner adopted the reasons in the Adjudication Officer's report and reaffirmed her denial of the requested second significant change. In their report, the Adjudication Officer once more cited an inconsistency with the SMFP and significant harm to VCU Hanover.

BSSM is one of 33 providers of CT services in PD 15 (**Table 1**) and one of eight providers of radiation therapy services in PD 15 (**Table 2**). In 2020, the last year for which the Division of Certificate of Public Need (DCOPN) has data available from Virginia Health Information (VHI), BSSM's four CT scanners operated at 133.7%% of the of the State Medical Facilities Plan (SMFP) utilization threshold (**Table 7**). During that same period, BSSM's one linear accelerator operated at 46.8% of the SMFP utilization threshold (**Table 8**).

Table 1. PD 15 COPN Authorized Fixed CT Units

Facility	Number of Scanners
Bon Secours Chester Emergency and Imaging Center	1
Bon Secours Imaging Center at Reynolds Crossing	1
Bon Secours Memorial Regional Medical Center	3
Bon Secours Richmond Community Hospital	1
Bon Secours Short Pump Emergency/Imaging Center	1
Bon Secours St. Francis Medical Center	2
Bon Secours St. Mary's Hospital[2]	4
Bon Secours Westchester Imaging Center	1
Buford Road Imaging	1
Chester Imaging Center	1
Chesterfield Imaging	1
Chippenham Hospital	3
Hanover Emergency Center	1
Henrico Doctor's Hospital - Parham Doctors' Hospital	1
Henrico Doctor's Hospital - Retreat	1
Henrico Doctors' Hospital - Forest	2
Independence Park Imaging	1
Virginia Cardiovascular Specialists	1
Johnston-Willis Hospital	3
Richmond Ear, Nose & Throat	1
Richmond Eye & Ear Healthcare Alliance d/b/a Medarva Healthcare	1
Swift Creek ER	1
VCU Health Neuroscience, Orthopedic and Wellness Center	1
VCU Health System[3]	9
VCU Medical Center Adult Outpatient Pavilion	1
VCU Medical Center at Stony Point Radiology	1
VCU Health Emergency Center at New Kent	1
Virginia Cancer Institute - Harbourside	1
Virginia Cancer Institute - Dominion Drive	1
Virginia Ear Nose & Throat - Chesterfield	1
Virginia Ear Nose & Throat - Henrico	1
Virginia Urology	2
West Creek Medical Center	1
Total	**53**

Source: DCOPN records

[2] The four CT scanners for Bon Secours St. Mary's Hospital includes one intraoperative CT scanner.
[3] The nine CT scanners located at VCU Health System includes one intraoperative CT scanner.

Table 2. PD 15 COPN Authorized Linear Accelerator Units

Facility	Number of Accelerators
Bon Secours Cancer Institute at Reynolds Crossing	1
Bon Secours Cancer Institute at St. Francis	1
Bon Secours St. Mary's Hospital	1
Henrico Doctors' Hospital - Forest	2
Johnston-Willis Hospital	3
Massey Cancer Center at Stony Point	1
VCU Health System	4
VCU Massy Cancer Center at Hanover Medical Park	1
Total	**14**

Source: DCOPN records

Proposed Project

The applicant proposes to establish a specialized center for radiation therapy services, Bon Secours Cancer Institute at Bell Creek (Bell Creek), through the relocation of one linear accelerator from BSSM and the addition of one new CT simulator. Bell Creek is located approximately 11.7 miles (25 minutes) from BSSM via the shortest route and approximately 17.1 miles (20 minutes) via the quickest route. Bell Creek is located 3.2 miles from VCU Massy Cancer Center at Hanover Medical Park (VCU Hanover). The total capital and financing cost of the proposed project is $13,083,667 (**Table 3**). The applicant states that the proposed project will be financed using the accumulated reserves of RROCI's owners. The applicant asserts that the project costs are not expected to impact the cost of providing care at the facility.

Table 3. Capital and Financing Costs

Direct Construction Costs	$4,171,250
Equipment Not Included in Construction Contract	$5,363,532
Site Acquisition Costs	$3,300,325
Architectural and Engineering Fees	$233,560
Other Consultant Fees	$15,000
TOTAL Capital and Financing Costs	**$13,083,667**

Source: COPN Request No. VA-8608

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the "[e]stablishment of a medical care facility described in subsection A." A medical care facility includes "[a]ny specialized center or clinic or that portion of a physician's office developed for the provision of… computed tomographic (CT) scanning… [and] radiation therapy…"

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;**

The applicant proposes to establish a specialized center for radiation therapy services through the relocation of one linear accelerator from BSSM and the addition of one CT simulator. The applicant asserts that the proposed project would offer a lower cost setting and would be reimbursed at lower rates than the hospital-based BSSM. The applicant additionally states that 39% of the patients that received cancer treatment at BSSM or Bon Secours Cancer Center at Reynolds Crossing (BSRC) originated from Bell Creek's primary service area (PSA). Moreover, the applicant states that, in 2021, BSRC's linear accelerator operated at 123% of the SMFP threshold. Given that BSRC's linear accelerator operated at 112.4% in 2020, the last year for which DCOPN has data available from VHI, DCOPN finds this assertion reasonable. The applicants assert that the relocation of the BSSM linear accelerator would allow them to decompress the heavily utilized linear accelerator at BSRC without the addition of a new linear accelerator.

Geographically, Bell Creek would be located at the intersection of Bell Creek Road and Autumn Park Way, approximately 1.2 miles from I-295, 3.3 miles from US-360, and 3.8 miles from US-301. The applicant states that no public transportation is currently available for Bell Creek, but that Hanover DASH service offers transportation to patients ages 60 and older upon request. The applicant does not address any benefits or drawbacks associated with parking at the proposed location.

The most recent Weldon-Cooper data projects a total PD 15 population of 1,219,936 residents by 2030 (**Table 4**). This represents an approximate 21.7% increase in total population from 2010 to 2030. Comparatively, Weldon-Cooper projects the total population of Virginia to increase by approximately 16.6% for the same period. With regard to Hanover County specifically, Weldon-Cooper projects a total population increase of 19,497, or approximately 19.5%, from 2010 to 2030. This total population increase is fourth among the areas listed in **Table 4** behind Chesterfield, Henrico, and Richmond City.

With regard to the 65 and older age cohort, Weldon-Cooper projects a total PD 15 population of 224,417 by 2030 (**Table 5**). This represents an approximate 30.3% increase in total population from 2010 to 2030. Comparatively, Weldon-Cooper projects the total population of Virginia to increase by approximately 27.4% for the same period. With regard to Hanover County specifically, Weldon-Cooper projects a total population increase of 14,352, or approximately 109.5% from 2010 to 2030. This total population increase is third among the areas listed in **Table 4** behind Chesterfield and Henrico. DCOPN notes that, while this ranking is higher than the total population cohort, Hanover's total population increase is less than half of the next highest area.

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

Table 4. PD 15 and Statewide Total Population Projections, 2010-2030

Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Charles City	7,256	6,982	-3.8%	6,941	-0.6%	-4.3%
Chesterfield	316,236	353,841	11.9%	396,647	12.1%	25.4%
Goochland	21,717	23,547	8.4%	26,702	13.4%	23.0%
Hanover	99,863	109,244	9.4%	119,360	9.3%	19.5%
Henrico	306,935	332,103	8.2%	363,259	9.4%	18.4%
New Kent	18,429	23,474	27.4%	28,104	19.7%	52.5%
Powhatan	28,046	29,909	6.6%	33,440	11.8%	19.2%
Richmond City	204,214	232,533	13.9%	245,483	5.6%	20.2%
Total PD 8	**1,002,696**	**1,111,633**	**10.9%**	**1,219,936**	**9.7%**	**21.7%**
Virginia	8,001,024	8,655,021	8.2%	9,331,666	7.8%	16.6%

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

Table 5. PD 15 Population Projections for 65+ Age Cohort, 2010-2030

Locality	2010	2020	% Change	2030	% Change	2010-2030 % Change
Charles City	1,214	1,773	46.1%	2,189	23.4%	80.3%
Chesterfield	32,878	55,297	68.2%	72,476	31.1%	120.4%
Goochland	3,237	5,420	67.4%	7,421	36.9%	129.3%
Hanover	13,104	19,807	51.2%	27,456	38.6%	109.5%
Henrico	37,924	53,255	40.4%	68,003	27.7%	79.3%
New Kent	2,226	4,303	93.3%	6,663	54.8%	199.3%
Powhatan	3,407	6,041	77.3%	8,552	41.5%	151.0%
Richmond City	22,619	26,352	16.5%	31,657	20.1%	40.0%
Total PD 8	**116,609**	**172,249**	**47.7%**	**224,417**	**30.3%**	**92.5%**
Virginia	976,937	1,352,448	38.4%	1,723,382	27.4%	76.4%

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

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 proposed project demonstrated by people, businesses, and governmental leaders representing the area to be served;

DCOPN received 10 letters of support from individuals and physicians associated with Bon Secours, which has an ownership interest in both of the co-applicants, one physician associated with NeuroSurgical Associates, P.C., and physicians associated with Virginia Urology, which has an ownership interest in RROCI. Collectively, these letters articulated the lack of a Bon Secours facility in the northeast part of the region. Moreover, these letters articulated the congestion at BSSM and the difficulties this causes for cancer patients.

Finally, these letters discuss the benefits of moving the linear accelerator from an inpatient to outpatient setting.

DCOPN received one letter of opposition from VCU Health System Authority (VCU). VCU notes that BSSM's prior two attempts to relocate this linear accelerator to Hanover County were denied by the Virginia State Health Commissioner (Commissioner) and alleges that this project is inconsistent with the SMFP, unnecessarily duplicates existing services, and would adversely impact existing providers in the area. The specifics of VCU's arguments and the applicants' submitted rebuttal are addressed in the relevant sections of this report.

On 3/17, DCOPN received a letter from VCU responding to the applicants' response to VCU's letter of opposition. As DCOPN's staff report is issued two business days from receipt of this letter, DCOPN did not have sufficient time to review, analyze, and incorporate the assertions made by VCU into this staff report.

Public Hearing

DCOPN provided notice to the public regarding this project on January 10, 2022. The public comment period closed on February 24, 2022. Section 32.1-102.6 of the Virginia Code mandates that "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, [DCOPN shall] hold one hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city." The proposed project is not competing, and no public hearing was requested by the applicant, the Commissioner, an interested party, or member of the public. As such, 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;

The proposed project marks the applicant's third attempt to relocate the linear accelerator from BSSM to this area of the planning district. The detailed history of these attempts are provided in section 2(v) below. One major issue that has continually been cited as a reason for why these previous projects were not approved by the Commissioner was the affect the proposed project would have on VCU's facility in the area. This issue was raised by VCU in their letter of opposition and, as discussed in detail below, DCOPN once more concurs with VCU's assertion that the proposed project would have a significant detrimental effect on VCU's facility.

As such, while the proposed project offers several significant benefits, DCOPN concludes that a preferable alternative to the proposed project would be the establishment of the proposed facility elsewhere in Eastern PD 15. This would still allow the applicants to provide a facility for patients within eastern PD 15, offer radiation therapy services at a lower cost to both patients and insurance providers than what is currently offered at BSSM, and decompress the BSRC linear accelerator while significantly reducing the affect that it would have on VCU's facility in the area. As shown in **Figure 2** below, there are large areas to the

east and southeast of PD 15 that are not proximate to an existing radiation therapy service provider that would still be closer to the patients in eastern PD 15. While outside the scope of the data provided, DCOPN also notes that no radiation therapy services are located in the southern part of the planning district. While DOCPN has no data for this service area from the applicants, depending on the patients that travel to Bon Secours from these areas, this absence of any other facilities in the area offers another alternative to the applicants' proposed project. As such, DCOPN concludes that relocation of the proposed project to an area less proximate to the VCU facility, or another existing facility, is a preferable alternative to the proposed project.

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

Currently there is no organization in HPR IV designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 15. Therefore, this consideration is not applicable to the review of the proposed project.

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

As discussed above, the total capital and financing cost of the proposed project is $13,083,667 (**Table 3**), which would be financed using accumulated reserves of RROCI's owners. The costs for the project are reasonable and somewhat consistent with previously approved projects to establish radiation therapy services through the addition of one linear accelerator with SRS/SRT capabilities and the addition of one CT simulator. For example, COPN VA-04223 issued to Inova Health System Hospital, Inc. to establish radiation therapy services at Inova Fair Oaks Hospital through the addition of one linear accelerator with SRS/SRT capabilities and the addition of one CT simulator, which cost approximately $11,490,551; and COPN VA-04245 issued to Medicorp Health System and Mary Washington Hospital to add one linear accelerator with SRS/SRT capabilities and one CT simulator, which cost approximately $11,030,326. While both projects are roughly two million dollars below the projected capital costs for the proposed project, these are related solely to the site acquisition costs for the Bell Creek project, which are absent in the two aforementioned projects. Regarding all other costs, the proposed project is the same, or slightly less, than the two projects. Based on the projected size of the proposed project and the costs of real estate within PD 15, DCOPN concludes that the site acquisition costs are reasonable. As discussed above, the proposed project would allow BSSM to decompress its heavily utilized linear accelerator at BSRC without the addition of a new linear accelerator to the PD 15 inventory. Moreover, the proposed project would offer a lower cost option with a lower reimbursement rate compared to the costs at BSSM.

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

According to regional and statewide data regularly collected by VHI, for 2020, the average amount of charity care provided by the facilities in HPR IV that reported such charity care

for that year was 1.3% of all reported total gross patient revenues. During this period, BSSM reported charity care of 2.54% of all reported total gross patient revenues (**Table 6**). In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project receive approval, Bell Creek is expected to provide a level of charity care for total gross patient revenues that is no less than the equivalent average for charity care contributions in HPR IV.

Table 6. HPR IV 2020 Charity Care Contributions

Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Bon Secours St. Francis Medical Center	$909,600,664	$28,930,399	3.18%
Bon Secours Richmond Community Hospital	$916,350,189	$28,612,659	3.12%
Bon Secours St. Mary's Hospital	$2,028,786,995	$51,459,409	2.54%
Bon Secours Memorial Regional Medical Center	$1,425,167,696	$28,386,279	1.99%
Centra Southside Community Hospital	$324,125,273	$5,447,210	1.68%
Sentara Halifax Regional Hospital	$279,469,170	$3,668,115	1.31%
CJW Medical Center	$7,560,037,769	$86,592,596	1.15%
VCU Health System	$6,172,966,084	$69,698,687	1.13%
John Randolph Medical Center	$1,032,491,952	$10,903,791	1.06%
Henrico Doctors' Hospital	$4,859,466,138	$51,444,601	1.06%
VCU Community Memorial Hospital	$317,168,977	$1,932,837	0.61%
Bon Secours Southern Virginia Regional Medical Center	$183,898,466	$1,059,319	0.58%
Bon Secours Southside Regional Medical Center	$1,875,804,250	$5,837,542	0.31%
Vibra Hospital of Richmond LLC	$145,408,947	$0	0.00%
Cumberland Hospital for Children and Adolescents	$54,279,874	$0	0.00%
Total $ & Mean %	**$28,085,022,444**	**$373,973,444**	**1.3%**

Source: VHI

(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 to 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, by November 1, 2022, 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.

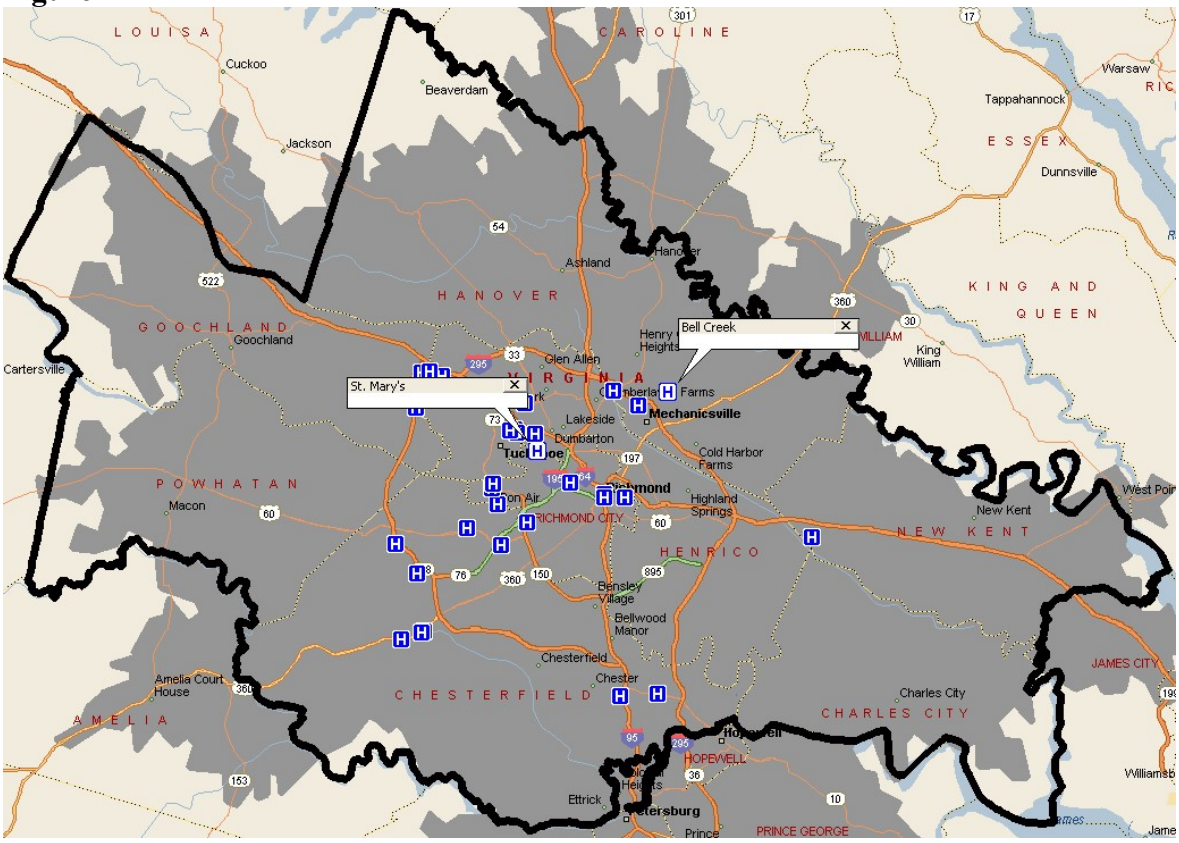
The SMFP contains criteria/standards for the establishment or expansion of CT services. They are as follows:

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.

Currently, there are 33 COPN authorized CT providers in PD 15. The heavy black line in **Figure 1** is the boundary of PD 15. The blue H icons indicate facilities that currently offer fixed CT services. The white H icon indicates the proposed facility. The grey shading illustrates the area that is within a thirty-minute drive one way under normal driving conditions of all CT service providers in PD 15. As the small areas of unshaded areas in **Figure 1** are located in sparsely populated areas, DCOPN concludes that it is likely that CT services are within a thirty-minute drive one way under normal driving conditions of 95% of the residents of the planning district. While a project that would introduce CT services to a new facility would generally increase access to some degree, the addition of a CT simulator that would be used solely for simulation with radiation therapy treatment is highly unlikely to materially affect access to CT services for those individuals not within a thirty-minute drive one way under normal driving conditions.

Figure 1



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.

Calculated Needed Fixed CT Scanners in PD 15
COPN authorized CT scanners = 53

Calculated Needed CT scanners =
344,235 scans in the PD / 7,400 scans / scanner = 43.2 (44) scanners needed

PD 15 Calculated Need = 44 CT scanners

PD 15 Calculated Surplus = 9 CT scanners

Table 7. PD 15 COPN Authorized Fixed CT Units: 2020

Facility	Number of Scanners	Number of Scans	Utilization Rate
Bon Secours Imaging Center Innsbrook	1	930	12.6%
Bon Secours Memorial Regional Medical Center	3	33,029	148.8%
Bon Secours Richmond Community Hospital	1	4,253	57.5%
Bon Secours St. Francis Medical Center	2	21,492	145.2%
Bon Secours St. Mary's Hospital	4	39,563	133.7%
Bon Secours Westchester Imaging Center	1	4,843	65.4%
Buford Road Imaging	1	569	7.7%
Chesterfield Imaging	1	5,140	69.5%
Chippenham Hospital	3	39,565	178.2%
Henrico Doctor's Hospital - Parham Doctors' Hospital	1	10,195	137.8%
Henrico Doctor's Hospital - Retreat	1	3,004	40.6%
Henrico Doctors' Hospital - Forest	4	29,547	99.8%
Independence Park Imaging	1	2,921	39.5%
Intecardia Life Imaging / Virginia Cardiovascular Specialists	1	3,445	46.6%
Johnston-Willis Hospital	2	27,362	184.9%
MEDARVA Imaging	1	34	0.5%
NOW Neuroscience, Orthopaedic and Wellness Center	1	1,932	26.1%
Richmond Ear Nose and Throat	1	301	4.1%
VCU Medical Center	7	67,365	130.0%
VCU Medical Center at Stony Point Radiology	1	4,992	67.5%
Virginia Cancer Institute - Harbourside	1	4,476	60.5%
Virginia Cancer Institute - Reynolds Crossing	1	6,135	82.9%
Virginia Ear Nose & Throat - Chesterfield	1	511	6.9%
Virginia Ear Nose & Throat - Henrico	1	563	7.6%
Virginia Urology	2	7,261	49.1%
2020 Total and Average	**44**	**319,428**	**98.1%**

Source: VHI & DCOPN interpolations

As noted in **Table 4** above, the utilization of existing CT scanners in the planning district was 98.1% of the 7,400 procedures per scanner necessary to introduce CT scanning services to a new location under this section of the SMFP. Additionally, DCOPN calculated a surplus of nine CT scanners in the planning district.

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 diagnostic CT scanners in PD 15 with respect to the proposed projects. Moreover, as the applicant has proffered that the CT scanner would be used solely for simulation with radiation therapy treatment, this exemption from the utilization criteria from 12VAC5-230-100.A above is applicable to this project.

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.

Not applicable. The applicant is not seeking to expand CT services at Bell Creek.

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 confirmed that CT simulation services would be under the direct supervision of one or more qualified physicians.

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

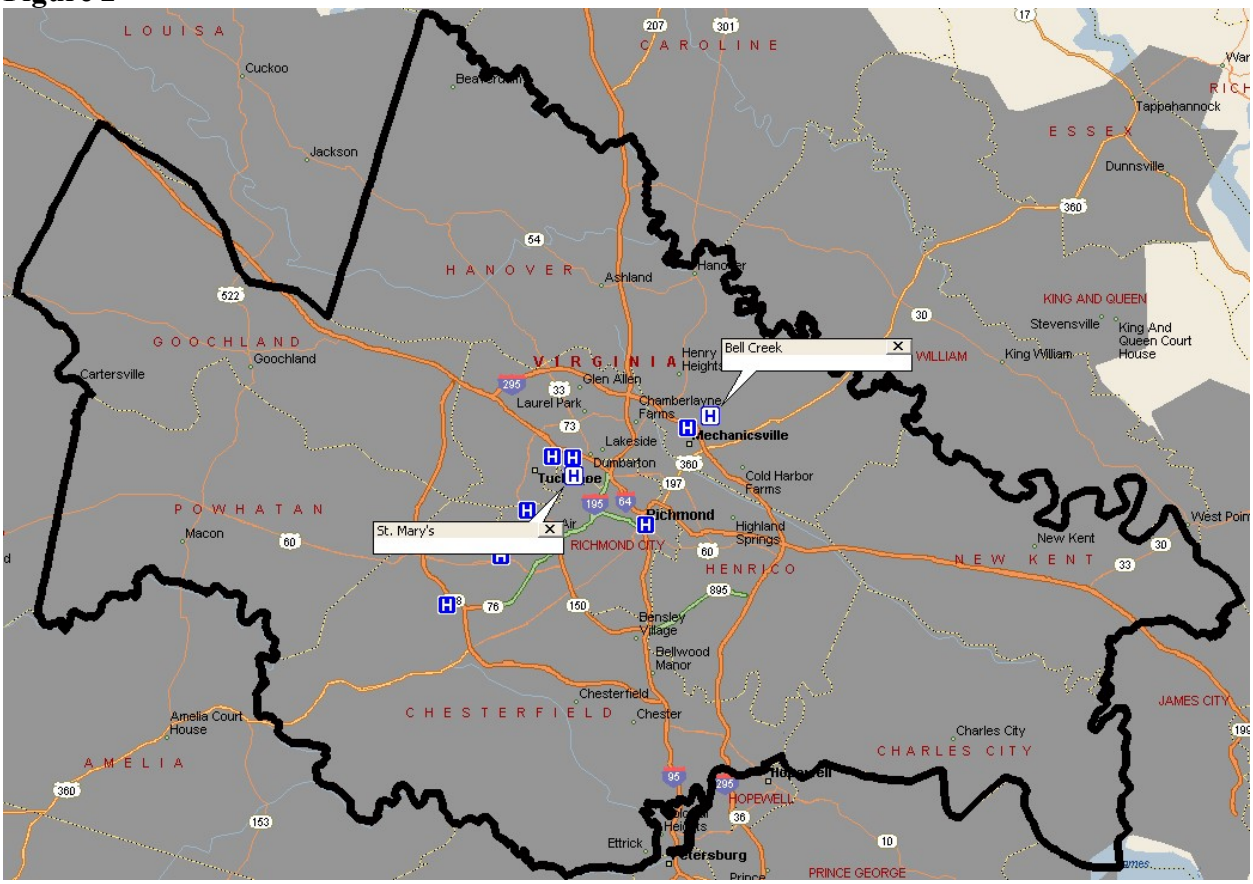
Part III
Radiation Therapy Services
Article 1
Criteria and Standards for Radiation Therapy Services

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.

Currently, there are two COPN authorized radiation therapy providers in PD 15. The heavy black line in **Figure 2** is the boundary of PD 15. The blue H icons indicate facilities that currently offer fixed radiation therapy services. The white H icons indicate BSSM and the proposed facility. The grey shading illustrates the area that is within a sixty-minute drive under normal driving conditions of all radiation therapy service providers in PD 15. **Figure 2** clearly illustrates that radiation therapy services are already well within a one-hour drive under normal conditions for all residents of the planning district.

Figure 2



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.**

The applicants are proposing to establish a specialized center for the provision of radiation therapy services. In 2020, the last year for which DCOPN has data available from VHI, the 12 linear accelerators in PD 15 operated at 62.8% of the SMFP threshold for this section. The applicant's calculations in this section of the SMFP, using the 2019 data, calculated a total of 72.3% of the SMFP threshold. The applicant additionally asserts that this equates to 8,670.6 treatment visits per provider, which is irrelevant as the division per provider is not contemplated in this section of the SMFP.

The applicants assert that their failure to meet this standard is irrelevant as the proposed project is inventory neutral and will not add to the total number of linear accelerators in the planning district. DCOPN disagrees with this assertion. No exception is made in the language of the

SMFP to differentiate between the establishment of a new service through the relocation of previously approved linear accelerators and the establishment of new service through the addition of a new linear accelerator. As this distinction is made elsewhere in the SMFP[4], *inclusio unius est exclusio alterius* would indicate that no such distinction was intended for this section when the SMFP was drafted. Moreover, the application of this standard to a relocation of an existing linear accelerator is vital in determining if a need exists for the relocated linear accelerator, both in the proposed area and in the planning district. As such, DCOPN concludes that the applicant does not meet this subsection of the SMFP. Regarding the projected utilization, VCU's objections, and the applicants' rebuttal, these will be discussed in detail in subsection C below.

Table 8. PD 15 COPN Authorized Linear Accelerators: 2020

Facility	Number of Accelerators	Number of Procedures	Utilization Rate[5]
Bon Secours Cancer Institute at Reynolds Crossing	1	8,989	112.4%
Bon Secours Cancer Institute at St. Francis	1	7,166	89.6%
Bon Secours St. Mary's Hospital	1	3,740	46.8%
Henrico Doctors' Hospital - Forest	2	8,705	54.4%
Johnston-Willis Hospital	3	13,306	55.4%
Massey Cancer Center at Stony Point	1	2,549	31.9%
VCU Massy Cancer Center at Hanover Medical Park	1	5,917	74.0%
VCU Medical Center	3	14,929	62.2%
2020 Total and Average	**13**	**65,301**	**62.8%**

Source: VHI & DCOPN interpolations

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 9 below shows the projected population and new cancer cases requiring radiation therapy in PD 15. Based on the SMFP methodology for determining need for linear accelerators in the

[4] 12VAC5-230-570
[5] Based on 8,000 procedure threshold at 12VAC5-230-290(A)

planning district, there is a need for 9 linear accelerators in PD 15 through 2025. As there are 14 COPN approved linear accelerators in PD 15, there will be a surplus of five linear accelerators in the planning district by 2025. Both VCU and the applicant calculated a surplus of three linear accelerators in the planning district by 2025. Neither party disputes that there is a calculated surplus in PD 15.

Table 9. Number of radiation therapy machines needed in PD 15

Locality	PD 15 Area 2025 Population	Cancer Incidence Rate (Per 100,000)	2025 Projected Cancer Cases	New Cancer Cases Requiring RT	Linear Accelerators Needed
Total PD 15	1,161,685	411.0	4,775	2,865	9

Source: U.S. Census, Weldon Cooper Center Projections (June 2019) and DCOPN (interpolations) and National Cancer Institute Incidence Rates Table (Latest Five-Year Average)

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.

The applicants anticipate performing 5,276 procedures in year one and 6,065 procedures in year two. The applicant states that these projections are based on the following factors:

- Patient origin for Bon Secours patients receiving radiation therapy services at Bon Secours facilities located north of the James River in PD 15, including St. Mary's and BSCI – Reynolds
- Historical utilization (e.g. treatment visits) of the St. Mary's and BSCI – Reynolds radiation therapy services
- Expected population growth for the projected BSCI – Bell Creek service area
- Expected new cancer cases for the projected BSCI – Bell Creek service area
- Expected radiation therapy growth in the projected BSCI – Bell Creek service area

The applicants additionally state that, because the proposed move is an inventory neutral relocation, they do not expect that approval of the project will have a negative impact on the utilization of other radiation therapy service providers in the planning district.

VCU argues that these projections rely on data that does not indicate a need for this project, are otherwise unsupported by data in the application, and are not attainable without significant adverse impact to VCU. VCU additionally states that the 15% growth between years one and two are not supported by data. VCU Hanover operated at 83.7% of the SMFP threshold in 2010 and VCU reports it operated at 69.8% of the SMFP threshold in 2021. DCOPN notes that VCU Hanover's report to VHI shows they operated at 52.8% of the SMFP threshold in 2019 and 74.8% of the SMFP threshold in 2020, the last two years for which DCOPN has data available from VHI (**Table 4**). VCU additionally states that projections from Sg2, a company that provides analytics and consulting services for medical professionals and hospitals, reflect at 10-year compound annual growth rate in outpatient radiation therapy treatments of 0.2% in the

service area, 0.1% in PD 15, and 0.05% in Virginia. VCU states that Sg2 shows that while population growth would influence growth, this is mitigated by innovation and technological advancement, which will result in a net decrease in patient volumes in the coming years.

The applicants, in response, state that they are unaware of how VCU manipulated the Sg2 data to reach these conclusions, and states that the Sg2 projects that radiation therapy cases in the Bell Creek PSA will increase by 0.4% a year. The applicants further state that, taking into account the dip in utilization in 2020, the growth should be even higher between 2021 and 2029, accounting for 1.3% annually. DCOPN does not accept the leap in logic of this second claim, as the growth would not necessarily "need to be made up" in subsequent years, particularly if the discussed dip in utilization is the result of a pandemic. The applicants additionally provide a more detailed breakdown on how the cases transferred from BSSM and BSRC would account for the majority of the projected cases.

As discussed above, Weldon Cooper data predicts that the population of Hanover County will increase by 19,497 between 2010 and 2030. **Table 4** above shows that Weldon Cooper data predicts that, between 2020 and 2030, the population of Hanover County will increase by 7,649. The cancer incidence rate for Hanover County, according to the National Cancer Institute Incidence Rates Table (Latest Five-Year Average) is 456.0 per 100,000. While unconventional, applying the new cancer cases requiring radiation therapy calculation found in subsection B above, DCOPN calculates, between 2020 and 2030, 21 additional cancer cases requiring radiation therapy over those ten years, or 2.1, rounded up to 3, cancer cases requiring radiation therapy per year, can be accounted for by the population growth in the planning district. This falls far below the growth projected by the applicant. DCOPN does not endorse this method for general use in determining the effects of population growth on radiation therapy volumes in a specific area of a planning district. In this specific instance, however, such an exercise is useful in determining the veracity of the conflicting claims made by the applicants and VCU regarding the population growth in the area, the effect on projected volumes, and their effect on VCU Hanover. As such, DCOPN concludes that the resulting projected procedures in year one are not accounted for in the decanted cases, as well as the growth indicated in year two, could not be the result of population growth based on Weldon Cooper data and projected cancer incidence rates for Hanover County.

VCU additionally argues that the proposed project would have a significant adverse impact on VCU Hanover. In support of this, VCU first provides a map showing that the projected PSA and secondary service area for Bell Creek overlaps with the majority of the service area for VCU Hanover. VCU next asserts that, in 2021, 73% of the radiation therapy treatment procedures performed at VCU Hanover originated within the proposed Bell Creak service area. Finally, VCU notes that the volumes at VCU Hanover have dropped significantly since the 2008 denial of COPN Request No. VA-7461 by the Commissioner.
The applicants argue that the proposed project will not adversely affect VCU Hanover based on the data discussed above. They additionally state that the proposed project is not duplicative as it will offer state of the art radiation therapy treatments at a lower cost than VCU Hanover. Regarding the state of the art radiation therapy statement by the applicants, DCOPN does not accept this argument as VCU could update their linear accelerator to a similar model without

additional COPN authorization. Nonetheless, based on the applicants' assertions and the lack of rebuttal on this matter from VCU, DCOPN must consider this assertion at the very least likely.

In such a case, DCOPN finds it highly unlikely that the proposed project and its associated projections could be effectuated without substantially harming the already underutilized VCU Hanover. As discussed above, the applicants' calculated cases that would be decanted from BSSM and BSRC, would not fully account for the totals in year one nor the growth in year two. Additionally, despite certain assertions by the applicant, the data available to DCOPN shows that there will be very little additional case volume generated by population growth in Hanover County. Moreover, the Bell Creek project is once more situated very close to VCU Hanover. Based on all these factors, DCOPN concludes that, while it is likely that the applicants will meet their projected thresholds, they will not be able to do so without significantly adversely affecting VCU Hanover. As such, DCOPN concludes that the applicant does not meet this threshold.

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.

Not applicable. The proposed project does not involve an expansion of a radiation therapy service.

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 Bell Creek will participate in the Statewide Cancer Registry consistent with all other Bon Secours Cancer Institute locations in PD 15.

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

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 there is only one provider in the immediate area of the proposed location, the proposed project would foster institutional competition. However, as discussed above, DCOPN ultimately

concluded that the proposed project is highly likely to reduce materially the utilization of this sole provider, who is currently operating well below the SMFP threshold. As such, while the proposed project would foster institutional competition, DCOPN ultimately concludes that this competition would not be beneficial.

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 discussed above, VCU, in their letter of opposition, asserted that the proposed project would materially reduce the utilization of VCU Hanover. This is a position that VCU has historically held and that the Commissioner has found to be accurate in past decisions. DCOPN, in its analysis above, once more concluded that the proposed project was highly likely to reduce materially the utilization of the one provider in the immediate vicinity of the proposed project, VCU Hanover.

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 10**) provided by the applicant projects a net profit of $369,498 by the end of the first year of operation and a net profit of $870,134 by the end of year two for the proposed project. The total capital and financing cost of the proposed project is $13,083,667 (**Table 3**). Approximately 32% of the total costs are attributed to direct construction costs and 25% of the total costs are attributed to the site acquisition costs. Approximately 41% of the total costs of the proposed project are attributed to the costs of equipment. The applicant states that the proposed project would be funded entirely using the accumulated reserves of RROCI's owners. Accordingly, there are no financing costs associated with the proposed project. Analysis of the financial documents provided with the application show that this method of funding the proposed project is viable. The applicant additionally asserts that the project costs are not expected to impact the cost of providing care at the facility. As such, DCOPN concludes that the proposed project is feasible with regard to financial costs in both the immediate and the long-term.

With regard to staffing, the applicant anticipates a need for 11 FTEs, including two FTEs for Registered Nurses, six FTEs for Radiologic Technologists, and one FTE for Dosimetrists. The applicant asserts that staffing requirements for the proposed project will be filled existing BSSM's radiation therapy staff. As the proposed project would result in linear accelerator treatment services no longer being offered at BSSM, DCOPN concludes that it is likely that a large portion of the staffing requirements can be met in this manner. For any additional requirements, the applicants state that:

> "Bon Secours and its affiliated and partnered entities across the Commonwealth utilize comprehensive recruitment methods, including advertisements in area newspapers, employment fairs at local health education schools and colleges, professional publications and journals, recruiting firms, etc. Recruitment efforts take place locally, regionally, statewide, and nationally as deemed necessary.

> Recruitment is also available through the [Bon Secours] website. In addition, Bon Secours and its affiliated and partnered entities operate a school of nursing health professions, and in addition partner with colleges, universities, and established allied health schools and programs. These partnerships have assisted Bon Secours recruit new staff into the area. Bon Secours maintains a system-wide "job board" so that Bon Secours employees nationwide can be made aware of opportunities throughout the enterprise."

While DCOPN recognizes that currently there is a national staffing shortage for nurses, given the modest requirements and the likelihood that staff will relocate to Bell Creek, DCOPN finds it likely that the nursing staffing requirement will be able to be met by the applicants without materially affecting existing providers. Concerning other staffing requirements, the methods proposed by the applicant are sufficiently robust to meet these staffing requirements without materially affecting existing providers. This determination is supported by the lack of opposition, regarding this particular issue, being raised by VCU or other providers. As such, DCOPN concludes that the proposed project's requirements are feasible and will not materially adversely affect existing providers.

Table 10. VHCEIC Pro Forma Income Statement

	Year 1	Year 2
Gross Revenue	$18,903,908	$21,730,895
Deductions from Revenue	$14,725,316	$16,879,380
Net Patient Services Revenue	**$4,178,592**	**$4,851,515**
Total Operating Expenses	**$3,809,094**	**$3,981,381**
Excess Revenue Over Expenses	**$369,498**	**$870,134**

Source: COPN Request No. VA-8608 & DCOPN interpolations

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 discussed above, the proposed project would move an existing linear accelerator from a hospital setting to an outpatient location. As such, the proposed project would improve the delivery of radiation therapy services on an outpatient basis. No other factors relevant to this section were identified by DCOPN or the applicant.

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.

The applicant does not raise any arguments or assertions that are relevant to this section. VCU makes the argument that insufficient patient volumes at VCU Hanover would adversely affect VCU's research and clinical trial opportunities. VCU does not provide any additional concrete information detailing what research and clinical trial opportunities could be affected by lowered utilization at a satellite location nor do they address what research and clinical opportunities are currently the result of the middling utilization at VCU Hanover that would cease to become available if the utilization further dropped. While DCOPN acknowledges the possibility that the proposed project would adversely affect VCU's research and clinical trial opportunities, VCU has not provided sufficient evidence for this consideration to affect materially DCOPN's decision.

DCOPN Staff Findings and Conclusion

DCOPN finds that the proposed project to establish a specialized center for radiation therapy services with one linear accelerator with SRS/SRT capabilities and one CT simulator is not consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. The applicant does not meet the criteria necessary for the establishment of a new medical care facility under 12VAC5-230-290. Moreover, based on all data available to DCOPN, the proposed project would significantly adversely affect an existing provider proximate to the Bell Creek location. Additionally, while DCOPN found the addition of the requested CT simulator was consistent with the SMFP, there is no public need for this limited use scanner without the proposed linear accelerator.

Moreover, DCOPN finds that the alternative of establishing the specialized center for radiation therapy in a location that is not proximate to an existing underutilized provider is a preferable alternative to the proposed project. This would still allow the applicants to provide a facility for patients within eastern PD 15, offer radiation therapy services at a lower cost to both patients and insurance providers than what is currently offered at BSSM, an decompress the BSRC linear accelerator while significantly reducing the affect that it would have on VCU's facility in the area. As shown in **Figure 2** above, there are large areas to the east and southeast of PD 15 that are significantly less crowded than the proposed location that would still be closer to their patients in eastern PD 15.

Finally, DCOPN finds that the total capital costs of the proposed project are $13,083,667 (**Table 3**), which would be financed using accumulated reserves of RROCI's owners. The costs for the project are reasonable and somewhat consistent with previously approved projects to add one CT scanner. For example, COPN VA-04223 issued to Inova Health System Hospital, Inc. to establish radiation therapy services at Inova Fair Oaks Hospital through the addition of one linear accelerator with SRS/SRT capabilities and the addition of one CT simulator, which cost approximately $11,490,551; and COPN VA-04245 issued to Medicorp Health System and Mary Washington Hospital to add one linear accelerator with SRS/SRT capabilities and one CT simulator, which cost approximately $11,030,326. While both projects are roughly 2 million dollars below the projected capital costs for the proposed project, these are related solely to the site acquisition costs for the Bell Creek project, which are absent in the two aforementioned

projects. Based on the projected size of the proposed project and the costs of real estate within PD 15, DCOPN concludes that the site acquisition costs are reasonable.

Staff Recommendation

The Division of Certificate of Public Need recommends **denial** of Richmond Radiation Oncology Center I LLC and Bon Secours-St. Mary's Hospital of Richmond LLC's COPN request to establish a specialized center for radiation therapy services with one linear accelerator with SRS/SRT capabilities and one CT simulator for the following reasons:

1. The project is not 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 project would significantly adversely affect an existing provider proximate to the Bell Creek location.

3. The establishment of the specialized center for radiation therapy in a location that is not proximate to an underutilized existing provider is a preferable alternative to the proposed project.

4. Without the requested linear accelerator, there is no public need for the requested CT simulator.