VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

March 21, 2025

RE: COPN Request No. VA-8798
Virginia Commonwealth University Health System Authority
Richmond, Virginia
Add 1 SRS capable linear accelerator

Applicant

The Virginia Commonwealth University Health Systems Authority ("VCUHS") is a public body corporate and political subdivision of the Commonwealth of Virginia, governed by the Virginia Commonwealth University Health System Authority Act of 1996-Title 23, Chapter 6.2, 23-50.16:1 of the Code of Virginia. The VCU Medical Center Adult Outpatient Pavilion ("AOP") is on the VCU Medical Center campus in Planning District (PD) 15, Health Planning Region (HPR) IV.

Background

A medical linear accelerator (LINAC) is the device most commonly used for external beam radiation treatments for patients with cancer. It delivers high-energy x-rays or electrons to the region of the patient's tumor. These treatments can be designed in such a way that they destroy the cancer cells while sparing the surrounding normal tissue. The LINAC is used to treat all body sites, using conventional techniques, intensity-modulated radiation therapy (IMRT), Volumetric Modulated Arc Therapy (VMAT), Image Guided Radiation Therapy (IGRT), Stereotactic Radiosurgery (SRS) and Stereotactic Body Radio Therapy (SBRT).[1]

The LINAC model proposed by VCUHS is SRS capable. SRS uses many precisely focused radiation beams to treat tumors and other problems in the brain, neck, lungs, liver, spine and other parts of the body. Doctors use three types of technology to deliver radiation during stereotactic radiosurgery in the brain and other parts of the body: LINAC, Gamma Knife and Proton Beam Therapy.[2] SRS "other than radiotherapy performed using a linear accelerator"[3] is regulated; thus, the SRS component of the LINAC is not addressed in this report.

---

[1] https://www.radiologyinfo.org/en/info/linac
[2] https://www.mayoclinic.org/tests-procedures/stereotactic-radiosurgery/about/pac-20384526#:~:text=Linear%20accelerator%20(LINAC)%20machines%20use,with%20a%20variety%20of%20conditions.
[3] § 32.1-102.1:3. Of the Code of Virginia.

According to Virginia Health Information (VHI), PD 15 had sixteen radiation therapy units in 2023, the latest year for which such data are available, across the various equipment options. There were thirteen LINAC-based radiation therapy machines (**Table 1**).[4] No changes have occurred to the PD 15 LINAC inventory since 2023, so the units documented by VHI are the LINAC units currently authorized in PD 15. The LINACs in PD 15 performed at 61.6% of the State Medical Facility Plan (SMFP) volume threshold of 8,000 procedures per unit (**Table 1**). VCUHS' utilization of its six LINACs was 46.1% of the SMFP standard in 2023.

Table 1. Linear Accelerators, PD 15, 2023

Facility Name	Class	Number of Machines	Visits	Visits/ Machine	% of SMFP
Bon Secours Cancer Institute at Reynolds Crossing	Linear with SR	1	8,495	8,495	106.2%
Bon Secours Cancer Institute at St. Francis	Linear with SR	1	9,336	9,336	116.7%
Bon Secours St. Mary's Hospital	Linear with SR	1	3,557	3,557	44.5%
Henrico Doctors' Hospital - Forest	Cobalt and Linear Accelerator without SR	1	512	512	6.4%
Henrico Doctors' Hospital - Forest	Linear with SR	1	5,923	5,923	74.0%
Johnston-Willis Hospital	Cobalt and Linear Accelerator without SR	1	6,595	6,595	82.4%
Johnston-Willis Hospital	Linear with SR	1	7,551	7,551	94.4%
VCU Massey Cancer Center at Hanover Medical Park	Cobalt and Linear Accelerator without SR	1	6,094	6,094	76.2%
VCU Massey Cancer Center at Stony Point	Cobalt and Linear Accelerator without SR	1	3,380	3,380	42.3%
VCU Medical Center	Cobalt and Linear Accelerator without SR	3	6,919	2,306	28.8%
VCU Medical Center	Linear with SR	1	5,723	5,723	71.5%
Totals and Averages, PD 15		**13**	**64,085**	**4,930**	**61.6%**

Source: 2023 VHI

Proposed Project

VCUHS proposes to add an SRS capable LINAC within the AOP on VCU Medical Center's downtown campus at 1001 East Leigh Street, Richmond, Virginia 23298. The 19-story building contains 26 outpatient specialties that were previously dispersed across the campus, including a site of the Massey Comprehensive Cancer Center. When the AOP was constructed, an empty vault was included for future expansion, so the proposed project will require only minor renovation and equipment installation. The applicant asserts that the capabilities of the proposed LINAC are not available elsewhere in the region and they enable adaptive radiation therapy, a revolutionary cancer treatment that uses daily imaging to adjust a patient's radiation plan for each treatment session, delivering a more accurate dose while minimizing damage to healthy tissue. The applicant states that the proposed CT image guided adaptive radiation therapy will enhance clinical care for patients,

[4] This excludes the gamma knife and two Variable (Superficial/Orthovoltage) machines that reported data to VHI.

including for SRS therapy patients and pediatric cancer patients, as well as VCUHS' physician education and research missions.

Capital costs of the proposed project are estimated to be $6,321,025 (**Table 2**), funded entirely by accumulated reserves, so no financing costs will be incurred. Should the proposed project be approved the applicant anticipates a target opening date 12 months after issuance of a COPN.

Table 2. Capital Costs, VCUHS SRS-Capable Linear Accelerator

Direct Construction Cost	$	721,025
Equipment not included in construction contract	$	5,500,000
Consultant Fees	$	100,000
Total Capital Cost	**$**	**6,321,025**

Source: COPN Request No. VA-8798

Project Definition

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

Required Considerations -- § 32.1-102.3, of the Code of Virginia

In determining whether a public need exists for a proposed project, the following factors shall be taken into account when applicable.

1. **The extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.**

PD 15 had a population over 1.1 million in 2020 and is projected to add nearly 100,000 to its population by 2030. Its projected growth of 8.9% by the end of the decade is a higher growth rate than that of Virginia's population, 5.8% (**Table 3**). Richmond City, where the proposed project is located, represents about 20% of the PD 15 population (**Chart 1**) and is projected to grow more slowly than PD15 as a whole at 8.3%, and add nearly 19,000 to its population between 2020 and 2030 (**Table 3**).

People aged 65 and older, are an important demographic in projects involving cancer care. Though the population over age 65 is expected to grow at a higher rate in PD 15 (31.7%) than that of Virginia (26.3%), this age cohort is projected to grow in Richmond by only 21.5%, far lower than Virginia's growth rate. Richmond is projected to add nearly 6,500 people over age 65 between 2020 and 2030 through aging and in migration (**Table 3/Chart 2**).

Table 3. Population by Locality, PD 15

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+
Charles City Co	6,773	6,200	-573	-8.5%	1,776	2,184	408	23.0%
Chesterfield Co	364,548	406,942	42,394	11.6%	58,200	78,858	20,658	35.5%
Goochland Co	24,727	27,339	2,612	10.6%	5,721	7,865	2,144	37.5%
Hanover Co	109,979	118,374	8,395	7.6%	20,688	28,681	7,993	38.6%
Henrico Co	334,389	356,656	22,267	6.7%	55,596	71,680	16,084	28.9%
New Kent Co	22,945	27,067	4,122	18.0%	4,405	6,216	1,811	41.1%
Powhatan Co	30,333	32,152	1,819	6.0%	5,848	8,085	2,237	38.3%
Richmond City	226,610	245,437	18,827	8.3%	29,874	36,307	6,433	21.5%
PD 15	**1,120,304**	**1,220,167**	**99,863**	**8.9%**	**182,108**	**239,876**	**57,768**	**31.7%**
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.

Chart 1. Percentage of PD 15 Population by Locality

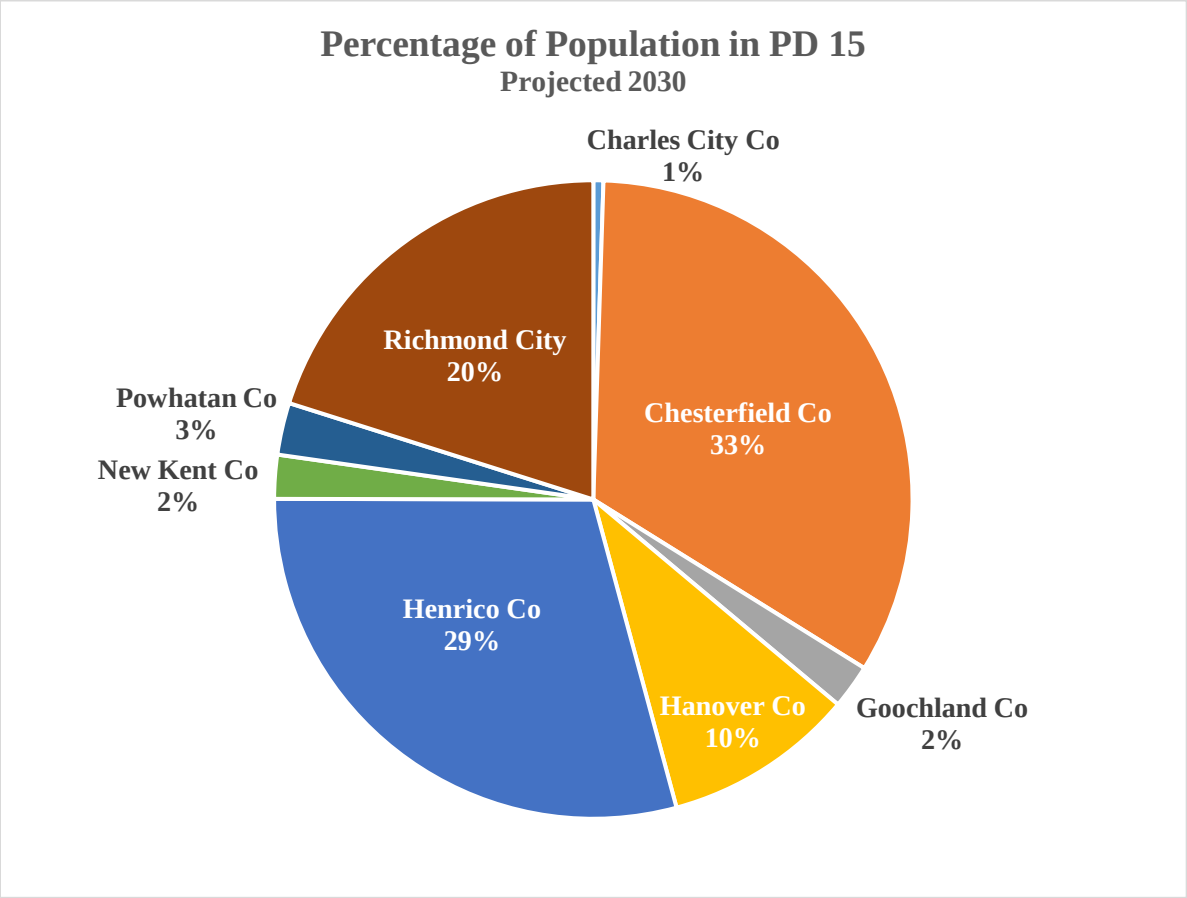


Chart 2. Projected Changes in Population 2020 to 2030, PD 15 Localities

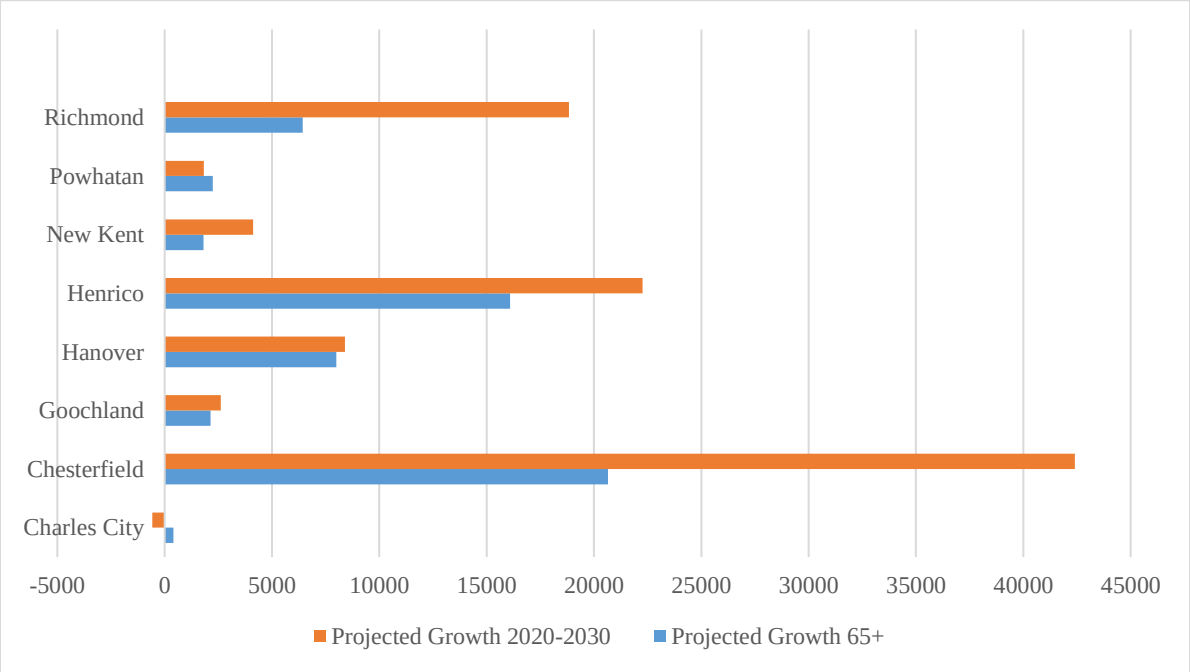


Table 4 shows that PD 15 has a poverty rate just under that of Virginia (10.7%), but the poverty rate in Richmond is more than double that of Virginia and of PD 15 at 24.5% As to transportation barriers, none are identified. AOP is on the corner of North 10th Street and East Leigh Streets on the VCU Medical Center campus in downtown Richmond. The facility is readily accessible from Interstates 64 and 95 as well as Broad Street making it accessible for all patients of Central Virginia or those traveling across Virginia. It is served by public transportation, including the Greater Richmond Transit Company ("GRTC") Pulse system, a modern rapid transit system that serves a 7.6-mile route along Broad Street and Main Street. The building is "steps away" from a GRTC bus stop connecting to all major GRTC bus routes for convenient access for the City of Richmond and surrounding communities.

Table 4. PD 15 Poverty Rates

Geographic Name	**Poverty Rate**
Charles City County	12.3%
Chesterfield County	7.6%
Colonial Heights City	13.5%
Goochland County	6.7%
Hanover County	5.2%
Henrico County	9.0%
New Kent County	5.2%
Powhatan County	6.9%
Richmond City	24.5%
PD 15 Totals	**10.1%**
Virginia	**10.7%**

Source: Weldon-Cooper Census Data

2. The extent to which the project will meet the needs of the residents of 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 a letter of endorsement from VCUHS' medical staff and two letters of support from the chair of the Department of Radiation Oncology at VCUHS and the president of the Children's Hospital of Richmond at VCU. These letters, in aggregate, expressed the following:

- VCUHS' medical staff strongly supports the addition of a LINAC with the latest CT-based adaptive radiotherapy technology.
- It will be the first of its kind in Virginia, better positioning VCUHS to fulfill its critical role in the community and further its clinical care, education and research missions.
- Radiation therapy is a cancer treatment that uses a LINAC to deliver high-energy x-rays to a target within a patient.
- Most LINACs are L-shaped with a treatment arm that rotates around the patient that can deliver adiation from multiple angles. The proposed LINAC is in a helical format, enabling the patient to move through the machine for CT-based adaptive radiotherapy.
- Adaptive radiotherapy adjusts the radiation plan in real-time to account for daily changes in the patient's body.
- It better enables the treatment team to account for changes in tumor size and position and to deliver the most accurate radiation dosage while minimizing exposure to normal tissue.
- This is increasingly important with complex tumor shapes and relationships to normal tissue structure, encountered routinely in our pediatric population.
- In addition to enhanced clinical care, the proposed LINAC is critical to VCUHS' education and research missions, better positioning it to help lead the evolution of innovative treatment approaches and clinical research that has significant impact on patient care and train the next generation of professionals.
- A radiation oncologist who has practiced at VCUHS for three decades states that most of their treatments delivered are with linear accelerator, and it is the departmental goal and obligation to have access to the latest technology for planning and treatment delivery of radiation oncology.
- He states it is "our responsibility to guarantee that we have the technology that allows us to lead in the provision of innovative treatment approaches."
- With current LINACs, VCUHS can deliver state-of-the-art inpatient and outpatient radiation services, including the use of 3D-conformaal, Intensity Modulated Radiotherapy, Stereotactic and Adaptive radiotherapy using MRI imaging.
- The requested LINAC will significantly enhance care delivery and advance teaching training and research opportunities.
- Children's Hospital of Richmond at VCU (VCUHS-CHoR) is the region's only pediatric cancer program, part of the VCU Massey Comprehensive Care Center.
- Radiation oncology is an important component of multidisciplinary care for our pediatric population.

- VCUHS-CHoR has an excellent pediatric radiation treatment program that involves the most sophisticated LINAC based treatment available, consistent anesthesia involvement and coordinated radiation oncology team.
- The proposed technology will address limitations, including the goal of delivering a sufficient radiation dose to the target while reducing the dose to surrounding tissue, more important in the pediatric population due to negative effect radiation has on growth and development.
- Pediatric tumors are typically adjacent to critical organs, regions that impact growth and are irregular and of complex shape.
- Pediatric patients require anesthesia for general management of treatment delivery to assure patient movement doesn't negatively impact accuracy.
- The helical CT-based adaptive LINAC promises decreased time on the table and less anesthesia needed, less associated risk.
- In addition to clinical benefits, the proposed LINAC will enhance pediatric cancer education and research programs.
- VCUHS-CHoR is one of only two programs in Virginia that train future pediatric cancer focused physicians.
- The addition of this technology promises improved treatment experience and treatment outcome.

Public Hearing

§32.1-102.6B of the Code of Virginia directs DCOPN to hold one public hearing on each application 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-8798 is not competing with another project and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing was held.

DCOPN provided notice to the public regarding this project inviting public comment on January 10, 2025. The public comment period closed on February 24, 2025. In addition to the letters of support summarized above, DCOPN received two letters of opposition to the proposed project within the public comment period, one from HCA Virginia Health System ("HCA Virginia") and one from Bon Secours Mercy Health ("BSMH").

HCA Virginia states in its letter that VCUHS does not demonstrate institutional need for an additional LINAC, having significant unused capacity on its existing authorized LINACs. It presents a table showing that VCUHS' four LINACs on its downtown campus operated at 39.5% of the SMFP threshold for expansion in 2023, down from 40.5% in 2022, according to VHI data. The letter notes that VCUHS has stated its two linear accelerators in the AOP serve the majority of its downtown population, but even these two LINACs operated at 79% of the SMFP standard in 2024 and will not reach 99% until 2027. HCA Virginia points out that VCUHS' application[5] for its latest authorized LINAC, an MRI-equipped LINAC (COPN No. VA-04596), anticipated shorter turnaround times for patients than those described in its current application. VCUHS' description

[5] COPN Request No. VA-8344

of its current use of the MRI LINAC is for "research and workflow innovation"[6] rather than routine patient care. HCA Virginia concludes that the LINAC has proved less useful than anticipated and suggests that it can be better utilized for additional patient treatments, or another reasonable alternative is the replacement of that underutilized technology with the proposed CT-based LINAC.

BSMH's letter of opposition presents similar concerns that the proposed project does not comply with the SMFP nor demonstrate institutional or community need, and that there are multiple effective alternatives that maximize existing LINAC capacity. BSMH provides a table demonstrating that VCUHS' six linear accelerators performed at 46% of the SMFP threshold for expansion in 2023. It references VCUHS' current application and its focus on only two of its six authorized LINACs in performing its utilization calculation for purposes of the proposed project. BSMH discusses specifically the utilization of VCUHS' MRI LINAC, authorized in 2018, which operated at 5% of the SMFP in 2023. BSMH further points out that VCUHS opposed BSMH's Bell Creek Project three years ago based on concerns about underutilized LINAC capacity in PD 15 and unrealistic volume projections given utilization trends in radiation oncology. In contrast, VCUHS' radiation therapy projections utilize a growth rate over time that is based on unusually high growth that occurred at AOP in the latest year, rather than overall visit declines consistent with trends over a longer period of time. The Bell Creek Project was denied and BSMH states that the same standards, scrutiny and rationale apply to VCUHS' current application. BSMH proposes the status quo, replacing the MRI LINAC, relocating the North Hospital LINAC to AOP or using it for more outpatients as reasonable alternatives the proposed project.

VCUHS sent a letter in response to the letters of opposition expressing the following:

VCUHS was created for the purpose of the support and delivery of medical care and related services, providing educational opportunities in the medical field and related disciplines, and conducting and facilitating research in the medical field and related disciplines. VCUHS' LINACs are not interchangeable with each serving a necessary purpose, and utilizing a strictly volume-based assessment, which VCUHS believes HCA Virginia and BSMH are advocating, would be a disservice to VCUHS' cancer patients and also inconsistent with COPN law, which requires consideration of multiple factors. VCUHS does not contest LINAC volumes below the SMFP standard due to purpose of each unit, the patient population being treated and inclusion of learners in treatment delivery. Both the Commissioner and DCOPN have recognized the shortcomings of the 16-year-old SMFP utilization threshold as treatments now extend beyond the 15-minute conventional radiation therapy session.

VCUHS points out that understanding its role as "Central Virginia's only academic health system" is essential to assessing need for the requested LINAC. Its clinical, educational and research mandates, patient mix, patient acuity and serving of indigent or underserved populations are required considerations in determining the need for innovative technology not otherwise available in Central Virginia. The letter asserts that its unique role in the region and the inherent limitations of new technologies impact the need for VCUHS' current complement of LINACs as well as its request to add a CT-guided LINAC. VCUHS included an affidavit of Douglas W. Arthur, M.D.

[6] COPN Request No. VA-8798, p. 30.

with its letter to "clarify misconceptions" about its linear accelerators' operation and to explain why the alternatives suggested by HCA Virginia and BSMH "are not reasonable, practical, efficient or in the best interests of patient care."

Douglas W. Arthur, M.D. is the Chair of the Department of Radiation Oncology at VCUHS and the Associate Director of Clinic Affairs within the Massey Comprehensive Cancer Center. He contests the premise of the letters of opposition that say VCUHS wants to disregard four of its six LINACs in the SMFP assessment. He says that, rather, VCUHS seeks acknowledgement that the LINACs are not interchangeable, and each serves a critical clinical, educational and/or research purpose for VCUHS and its patients. He asks that the Commissioner, consistent with her discretion, recognize that these purposes don't lend themselves to high utilization. For example, the complexities of VCUHS' patients require different protocols; clinical trials can require additional imaging and quality confirmation protocols; as a teaching institute, appropriate training of dosimetrists, therapists and physicist learners requires their participation in treatment delivery which adds time and reduces throughput and usage.

VCUHS' most recently authorized LINAC, the ViewRay MRI LINAC, is one of only 50 in operation in the country. It provides real-time imaging and tracking of a patient's tumor, adjusting for breathing or bowel movements. It is the most clinically appropriate for some patients, but its use requires hours of planning and protocols that Dr. Arthur admits were not anticipated until the unit was operationalized, limiting the number of treatments that can be performed. VCUHS confirms that its 2023 utilization was 5% of the SMFP threshold. Another suggested alternative in the letters of opposition was relocating VCUHS' inpatient LINAC, which is not at capacity, but that option would subject inpatients to risky and inefficient transport. It would be more costly for patients and reduce quality care. Requiring outpatients to navigate the complex inpatient building is likewise not the best patient care or experience. Dr. Arthur states that radiation therapy is predominantly an outpatient service. Not only is the AOP where the empty vault is located, it is where, despite extending treatments to late nights and weekends, VCUHS' outpatient LINACs lack functional capacity.

Dr. Arthur addresses BSMH's critique that VCUHS' projections are unreasonable and unsupported by itemizing factors VCUHS considered in its projections: utilization, trends and growth rates on all of VCUHS' LINACs (some of which exceed the growth rate used), overall growth in cancer incidence and high-acuity patient mix of VCUHS' patients, evolving treatment protocols and all relevant metrics relating to patient visit volumes, treatments per patient, length of treatments, treatment courses and new patient encounters. Dr. Arthur also clarifies that VCUHS' opposition to BSMH's 2022 proposal to relocate a LINAC from Bon Secours St. Mary Hospital to a new site in Hanover was due to proximity to VCUHS' existing radiation therapy site (two miles) and lack of evidence of an existing Bon Secours patient base in addition to the PD need threshold. These factors supported the conclusion that BSMH's project was likely have significant negative impact on volumes of existing providers.

(ii) The availability of reasonable alternatives to the proposed service or facility that would meet the needs of the population in a less costly, more efficient, or more effective manner.

The most reasonable alternative to the proposed project is to remove the underutilized ViewRay MRI LINAC from clinical use and place the proposed CT based LINAC in the existing empty vault previously constructed for expansion. This option would "substitute" the CT based LINAC that has higher potential for throughput and thus add outpatient treatment capacity without adding a LINAC to the VCUHS or PD 15 inventory (i.e, it would not require a COPN). This alternative would add the "online" capability described in COPN Request No. VA-8798, that is, the ability to adapt the patient's treatment while the patient remains on the treatment couch immediately following CT guidance. This is a capability that the applicant describes as particularly beneficial to VCUHS' pediatric population and not otherwise available in PD 15.

Installing the proposed CT-based SRS capable LINAC and replacing the ViewRay MRI LINAC, however, would require the same capital investment as implementing the proposed project without taking the ViewRay MRI LINAC out of service. It would also eliminate the availability to appropriate patients of the MRI LINAC's "inline" approach, that is, visualization and targeting simultaneously with the radiation treatment taking place. VCUHS has a unique role as an academic medical center with clinical, research and educational missions. The proposal contributes to all three of these missions, promising state-of-the-art technology in clinical care; enabling additional clinical trials in radiation oncology to develop and improve treatments; and supporting VCUHS' ability to educate the radiation oncology workforce, preparing them for standards of care in the future. Replacing the ViewRay MRI LINAC would eliminate the training opportunities for radiation therapy learners, future providers, in the MRI based technology. This alternative is not less costly, more efficient nor more effective than the proposed project. It only serves to preserve the PD 15 inventory at 13 LINACs rather than adding the 14th.

The proposal is also more beneficial than the status quo in bringing patients, in particular pediatric cancer patients, the online capability of the proposed CT based LINAC not otherwise available in PD 15. Therefore, DCOPN concludes that there is no reasonable alternative to the proposed project that is less costly, efficient or effective.

(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 project.

Total projected capital cost for the proposed project is $6,321,025, funded in its entirety with accumulated reserves, such that there are no financing costs involved in the proposed project. The estimated costs are consistent with other recently approved projects to add a LINAC at an established facility, within the range of COPN Nos. VA-04859 at $6.8 million and VA-04839 at $3.3 million, for example.

The applicant has described several benefits to the proposed project, including the addition of technology not otherwise available in the region. The proposed LINAC enables CT image guided "online" adaptive radiation therapy, which adjusts the radiation plan based on imaging that occurs during the same treatment session/day to maximize radiation dosage to the target site and spare the most healthy tissue. VCUHS describes this technology as particularly suitable and beneficial for its pediatric patients, having the minimum negative impact on growth and development and decreasing the amount of anesthesia needed for these patients' treatments. The applicant asserts that VCUHS is the region's only academic medical center and tertiary/quaternary referral center, as well as the largest safety net hospital in Virginia. It describes the proposed project as an investment that contributes to leading clinical research and educating the radiation therapy focused workforce for standards of care of the future. In addition, the applicant hopes to alleviate high demand for the two (non-MRI) linear accelerators at AOP.

(v) The financial accessibility of the project to the residents of the area to be served, including indigent residents.

VCUHS states that it cares for significant numbers of medically and socio-economically challenged patients. VCU Health System provided charity care in 2022 at 0.6% of gross patient revenues (including 0.2% of VCU Community Memorial's gross patient revenue and 0.1% of VCU Health Neuroscience, Orthopedic and Wellness Center's), less than the HPR IV average of 0.9% (**Table 5**). The proforma provided (**Table 6**) assumes charity care for the proposed project, consistent with the HPR IV charity care contribution average in 2022, the latest year for which such data are available.

In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project receive approval, the project would be conditioned to provide a level of charity care based on gross patient revenues derived from radiation therapy that is no less than the equivalent average for charity care contributions in HPR IV of 0.9%. Pursuant to Code of Virginia language any COPN issued for this project will also be conditioned on the applicant's agreement to accept patients who are the recipients of Medicare and Medicaid.

Table 5. HPR IV Charity Care Contributions: 2022

2022 Charity Care Contributions at or below 200% of Federal Poverty Level			
HPR IV	**Gross Patient Revenues**	**Adjusted Charity Care Contribution**	**Percent of Gross Patient Revenue**
Inpatient Hospitals			
Encompass Health Rehab Hosp of Petersburg	$29,926,632	$1,262,680	4.2%
Bon Secours Southern Virginia Regional Medical Center	$226,835,907	$4,487,576	2.0%
Sheltering Arms Institute	$151,399,824	$2,530,945	1.7%
Sentara Halifax Regional Hospital	$309,122,102	$4,945,782	1.6%
Bon Secours St. Francis Medical Center	$1,238,984,979	$19,560,168	1.6%
Bon Secours St. Mary's Hospital	$2,475,071,483	$27,800,876	1.1%
Bon Secours Southside Regional Medical Center	$2,238,925,486	$23,176,465	1.0%
CJW Medical Center HCA	$9,414,749,474	$92,280,367	1.0%
TriCities Hospital HCA	$1,291,681,768	$12,190,500	0.9%
Bon Secours Richmond Community Hospital	$1,099,525,303	$9,999,109	0.9%
Henrico Doctors' Hospital HCA	$6,125,759,528	$50,390,024	0.8%
Bon Secours Memorial Regional Medical Center	$1,648,605,572	$10,986,041	0.7%
VCU Health System	$7,574,785,954	$45,509,855	0.6%
Poplar Springs Hospital UHS	$84,621,465	$328,036	0.4%
Centra Southside Community Hospital	$357,467,950	$1,261,207	0.4%
VCU Community Memorial Hospital	$428,496,287	$664,258	0.2%
Encompass Health Rehab Hosp of Virginia	$28,839,933	$35,972	0.1%
Select Specialty Hospital - Richmond	$119,460,229	-	0.0%
Cumberland Hospital for Children and Adolescents UHS	$32,427,799	-	0.0%
Total Inpatient Hospitals:			19
HPR IV Total Inpatient $ & Mean %	$34,876,687,675	$307,409,861	**0.9%**
Outpatient Centers			
Boulders Ambulatory Surgery Center HCA	$133,673,934	$3,982,385	3.0%
Urosurgical Center of Richmond	$46,192,499	$467,587	1.0%
Virginia Eye Institute, Inc.	$41,539,958	$362,746	0.9%
St. Mary's Ambulatory Surgery Center	$51,111,602	$420,544	0.8%
MEDRVA Surgery Center @ West Creek	$11,215,428	$27,326	0.2%
VCU Health Neuroscience, Orthopedic and Wellness Center	$6,301,892	$9,063	0.1%
American Access Care of Richmond	$5,218,308	$865	0.0%
Cataract and Refractive Surgery Center	$9,709,070	-	0.0%
MEDRVA Stony Point Surgery Center	$62,279,534	-	0.0%

Skin Surgery Center of Virginia	$1,562,293	-	0.0%
Virginia Beach Health Center VLPP	$2,518,016	-	0.0%
Total Outpatient Hospitals:			11
HPR IV Total Outpatient Hospital $ & Mean %	$371,322,534	$5,270,516	**1.4%**
Total Hospitals:			30
HPR IV Total $ & Mean %	$35,248,010,209	$312,680,377	**0.9%**

Source: VHI 2022

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

There are no other factors, not addressed elsewhere in the analysis, relevant to the determination of a public need for either project.

3. The extent to which the application is consistent with the State Medical Facilities Plan.

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

The State Medical Facilities Plan (SMFP) contains the criteria and standards for radiation therapy services. They are as follows:

Article 1
Radiation Therapy Services

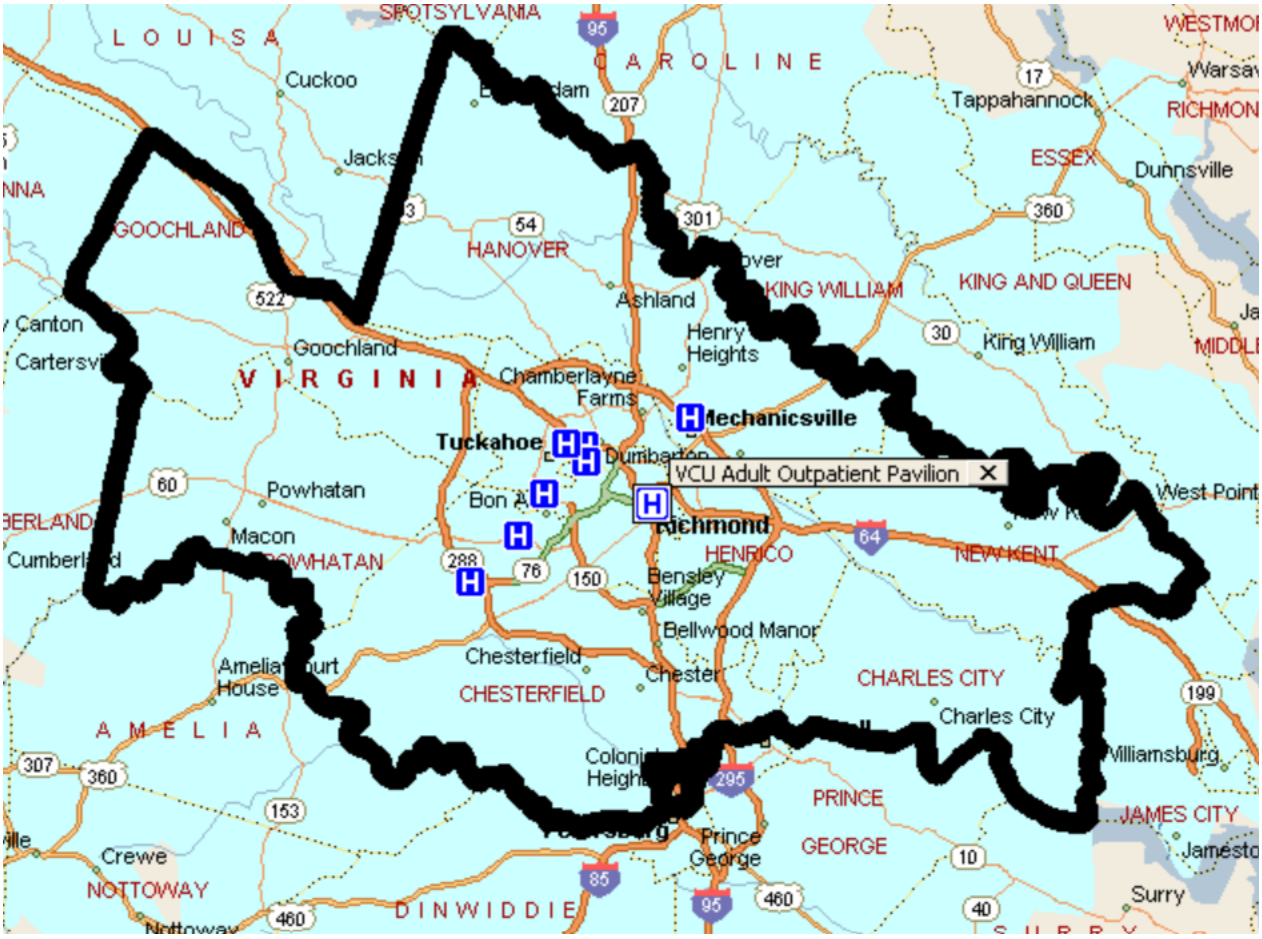
12VAC5-230-280. Travel time.

Radiation Therapy Services

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.

Figure 1 shows the boundary of PD 15, the heavy black line. Authorized radiation therapy sites in PD 15 are represented by the blue icons and the proposed project at AOP is located by the white icon with the blue H. The light blue shading shows the area that is within 60 minutes' drive time of a PD 15 LINAC site. The map shows that the entirety of PD 15 is within 60 minutes driving time of a radiation therapy service. The proposed project at an existing site does not expand access beyond the geographic area already within 60 minutes' driving time of a radiation therapy service. VCUHS states that the proposed unit will allow VCUHS to provide adaptive radiation therapy unavailable elsewhere in the region, though the SMFP does not make a distinction between this state-of-the-art treatment and conventional radiation therapy.

Figure 1. Map of Authorized Linear Accelerators, PD 15



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

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

1. Existing radiation therapy machines located in the health planning district performed an average of 8,000 procedures per existing and approved radiation therapy machine in the relevant reporting period; and

2. The new service will perform at least 5,000 procedures by the second year of operation without significantly reducing the utilization of existing providers in the health planning district.

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

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

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

Not applicable. VCUHS is not proposing a new service, rather the expansion of an existing service. For the sake of being thorough, the number of radiation therapy machines is calculated as follows:

(PD 15 Population (2030) X PD 15 Incidence Rate X 0.6)/320

(1,220,167 X 449.74/10000) X 0.6/320 = 10.29 (11)

Current Inventory = 13
13 Current Inventory – 11 Needed = Surplus of 2

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.

According to VHI, PD 15 LINACs performed an average of 4,930 visits per unit in 2023 (**Table 1**), the latest year for which such data are available. This is 61.6% of the utilization threshold for expansion. VCUHS argues that the SMFP's utilization standard for radiation therapy is based on conventional radiation therapy visits with a presumed capacity of 32-34 patients per day and 25 fractions as a typical course of treatment. The applicant sites a statement by the DCOPN from 2014 that "determining the need for linear accelerators based solely on the conventional 25-visit treatments is no longer a workable method…"[7]

VCUHS' six LINACs performed at 46.1% of the SMFP standard for expansion, lower than the PD 15 average. VCUHS has argued that four of its six LINACs should be excluded from the SMFP calculation. The LINACs at the Massey Comprehensive Cancer Center locations in Hanover and

[7] DCOPN Staff Report on COPN Request No. VA-8103, pp. 5-6.

Stony Point are off-campus, 8.7 miles and 10.5 miles, respectively, from the AOP serving outpatient satellite locations.

The LINAC in North Hospital serves an inpatient population with complex needs, including urgent radiation treatments for difficult-to-control cancers in adults and children, total body irradiation for bone marrow transplant patients, and immediate post-operative radiation following certain surgical repairs. The applicant argues that this LINAC is necessarily placed in the inpatient setting to serve inpatients safely without the risk of transport and has lower utilization than the units that serve outpatients at AOP by virtue of its unique and smaller patient base. Finally, VCUHS uses its MRI LINAC, authorized in 2018, for "clinical research and workflow innovation" and confirms that it is also used for patient care on clinically appropriate patients. The applicant states that the unit has workflow limitations as it requires several hours of pre-scan planning and protocols, and it is not designed to achieve the same volumes as the other two outpatient LINACs in the AOP. The two remaining LINACs at AOP operated at 73% of the SMFP standard in 2023 and 79% in 2024.

Though there is opposition to the proposed project from both HCA Virginia and BSMH based upon VCUHS' failure to exceed the SMFP threshold, it is notable that neither opposition letter claimed that the project would significantly harm utilization of existing providers of radiation therapy.

While the applicant does not meet the computational analysis of this SMFP standard, DCOPN recommends that the Commissioner, in this specific instance, does not allow this standard to bar the addition of this CT guided SRT capable LINAC.

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.

VCUHS' cancer services participate in the Statewide Cancer Registry and the applicant provides assurances it will continue to do so.

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.

VCUHS will continue to be under the direction and supervision of one or more board-certified radiation oncologists and physicists in accordance with this provision.

Required Considerations Continued

4. **The extent to which the proposed service or facility fosters institutional competition that benefits the area to be served while improving access to essential health care services for all persons in the area to be served.**

VCUHS, with its Massey Comprehensive Cancer Center, has more LINACs than any other provider of radiation therapy in PD 15. The proposed project does not foster beneficial institutional competition but adds to the provider with the largest LINAC inventory in PD 15. Due to its large and unique patient base including complex and pediatric cancer care, the proposal is unlikely to impact volumes of existing providers of radiation therapy.

5. **The relationship of the project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities.**

VCUHS asserts that it is the only academic medical center in the region and serves as a tertiary/quaternary referral center over a large geography. VCUHS' Massey Cancer Center is a National Cancer Institute (NCI)-designated cancer research and treatment center that is internationally recognized and has been given NCI's highest designation as a Comprehensive Cancer Center, ranking among the top four percent of all cancer centers in the country. VCUHS works with all types of cancers, including the most complex and rare, and with adult and pediatric populations. The Massey Comprehensive Cancer Center occupies six floors of the AOP. VCUHS provides state-of-the-art cancer care, cutting edge clinical trials and, as an academic medical center, provides oncology education, teaching and training for future clinicians.

As discussed in its application and response to letters of opposition, utilization of VCUHS' LINACs is less than most other sites in PD 15 due to each LINAC serving a specific population, such as geographically or inpatient specific; and the additional mission obligations VCUHS has as an academic medical center, such as clinical research protocols, the involvement of learners, and throughput limitations of newer technology.

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

Capital costs for the proposed project are reasonable within the range of recently authorized, similar projects to add a LINAC to an existing site. The proforma provided by the applicant (**Table 6**) projects a net income for the proposed project approaching $1.8 million its first year and $1.9 million its second year. The proposal would require 7 additional full-time equivalent staff members to operationalize, which VCUHS is capable of recruiting.

Table 6. Proforma, VCUHS SRS-Capable Linear Accelerator

	Year 1	Year 2
Gross Revenue	**$ 12,299,138**	**$ 13,657,310**
Charity Care	$ 110,692	$ 122,916
Other Deductions	$ 8,615,446	$ 9,566,834
Total Net Revenue	**$ 3,573,000**	**$ 3,967,560**
Total Expenses	**$ 1,797,717**	**$ 2,092,434**
Net Income Before Taxes	**$ 1,775,283**	**$ 1,875,126**

Source: COPN Request No. VA-8798

7. **The extent to which the project provides improvements or innovations in the financing and delivery of health 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 services on an outpatient basis. (iii) Any cooperative efforts to meet regional health care needs. (iv) At the discretion of the Commissioner, any other factors as may be appropriate.**

The proposal introduces a LINAC capable of providing CT image guided "online" adaptive radiation therapy, a new technology in PD 15. The technology promises better outcomes for patients with complex tumors and particularly pediatric patients as the radiation plan is adjusted, effectively in real time, to account for changes in the patient's body. It delivers the most accurate radiation dosage while minimizing exposure to normal tissue. For pediatric patients, it reduces the impact of treatment on growth and development and enables less anesthesia. The proposed LINAC would provide services on an outpatient basis.

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.

VCUHS is an academic medical center with clinical, research and educational missions. The proposal contributes to all three of these missions, promising state-of-the-art technology that better targets tumors and spares healthy tissue in clinical care; enabling additional clinical trials in radiation oncology to develop and improve treatments; and supporting VCUHS' ability to educate the radiation oncology workforce, preparing them for standards of care in the future. The applicant states that, as the largest safety net hospital in Virginia, it cares for significant numbers of medically and socio-economically challenged patients.

DCOPN Staff Findings and Conclusions

Virginia Commonwealth University Health Systems Authority proposes to add a seventh LINAC, an SRS capable LINAC that offers CT guided adaptive radiotherapy (ART) on its downtown campus in Richmond, Virginia at the AOP. The CT guided LINAC promises better tumor targeting and sparing of healthy tissue combined with patient throughput. The technology is especially beneficial for stereotactic body radiation therapy and pediatric patients, and the capabilities of the proposed LINAC are not available elsewhere in the region.

PD 15 is an area of Virginia that is growing at a rate higher than that of Virginia and the important 65 and older demographic is also growing faster than the Virginia growth rate for that age group. Richmond has socioeconomic barriers, with a poverty rate more than double that of the state. The proposed project falls short of the volume threshold set forth in the SMFP to expand an existing service, and there is opposition to the proposal primarily for this reason. Opponents of the project, however, do not claim that its approval will cause them significant harm. DCOPN has not identified a reasonable alternative that is less costly, more efficient and more effective than the proposed project. It is more beneficial than the status quo. Capital costs of the proposed project are reasonable and consistent with similar, recently approved projects. It is financially feasible in the immediate and long term.

The applicant has a unique role in the region and in the Commonwealth. VCUHS is an academic medical center with research and education missions in addition to clinical care, one of the eight considerations required by the Code of Virginia. In addition, VCUHS' Massey Cancer Center is an NCI-designed Comprehensive Cancer Center ranking among the top four percent of all cancer centers in the country. VCUHS works with all types of cancers, including the most complex and rare, and with adult and pediatric populations. It performs clinical research and incorporates learners into its operations. Though these factors do not mean that approval of any new technology is merited, the proposed project improves access to unique outpatient radiation therapies that have throughput barriers directly related to VCUHS' research, educational and technology obligations. The proposal brings innovations in the delivery of health services, introducing new technology that promotes quality in the delivery of health care services, another required consideration.

While the applicant does not meet the computational analysis of the SMFP standard, the proposal's contributions to delivery of care and access to an academic medical center are unique. DCOPN recommends that, in this specific instance the SMFP standard not bar the addition of the proposed LINAC.

DCOPN Staff Recommendations

The Division of Certificate of Public Need recommends **conditional approval** of Virginia Commonwealth University Health System Authority's COPN Request No. VA-8798 to expand its radiation therapy service with the proposed SRS capable linear accelerator, in the Adult Outpatient Pavilion on its campus in Richmond, Virginia for the following reasons:

1. The proposal to add an SRS capable linear accelerator with CT guided adaptive radiotherapy in the Adult Outpatient Pavilion on VCUHS' campus contributes to the unique research, training,

and clinical mission of an academic medical center and furthers delivery, innovation, and improvement of health care for citizens of the Commonwealth, including indigent or underserved populations.

2. The proposal is generally consistent with the applicable standards and criteria of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.

3. The proposal introduces new technology that promotes quality in the delivery of healthcare at an NCI-designated Comprehensive Cancer Center as well as delivery of radiation therapy on an outpatient basis.

4. The proposal improves access to radiation therapy in a high-growth area of Virginia.

5. The capital costs of the proposed project are reasonable, and it appears to be wholly viable in the immediate and long-term.

6. The proposed project is unlikely to have a significant negative impact upon the utilization, costs, or charges of other providers of radiation therapy services in PD 15.

DCOPN's recommendation is contingent on Virginia Commonwealth University Health System Authority's agreement to the following charity care condition:

> Virginia Commonwealth University Health System Authority will provide radiation therapy 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 will facilitate the development and operation of primary medical care services to medically underserved persons in PD 15 in an aggregate amount equal to at least 0.9% of Virginia Commonwealth University Health System Authority's gross patient revenue derived from radiation therapy services. Compliance with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement. Virginia Commonwealth University Health System Authority 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 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.
>
> Virginia Commonwealth University Health System Authority will provide radiation therapy care 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. Virginia Commonwealth University Health System Authority

will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.