

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

March 21, 2023

RE: COPN Request No. VA-8684

Inova Health Care Services d/b/a

Inova Loudoun Hospital

Woodbridge, Virginia

Expansion of Radiation Therapy Services Through Addition of One Linear Accelerator

Applicant

Inova Health Care Services (“Inova HCS”), a 501(c)(3) Virginia nonstock corporation, owns Inova Loudoun Hospital (“ILH”). The sole member of IHCS is the Inova Health System Foundation, also a 501(c)(3) Virginia nonstock corporation. The proposed project is located at 44035 Riverside Parkway, Suite 100, Leesburg Virginia 20176, within Planning District (“PD”) 8, embedded in Health Planning Region (“HPR”) II.

Background

Linear Accelerator

A linear accelerator uses microwave technology (similar to what is used for radar) to accelerate electrons in a part of the accelerator called the “wave guide”; these electrons then collide with a heavy metal target to produce high-energy x-rays.¹ These medical linear accelerators (LINAC) are most commonly used for external beam radiation treatments for patients with cancer; the beams can be targeted to destroy cancer cells while sparing the surrounding normal tissue from direct contact with the beam.² Per the applicant, current radiotherapy delivery systems are image-guided, dual-energy, high-dose, multifunctional LINACs optimized for 3D conformal radiation therapy and stereostatic applications; stereostatic applications include single session radiosurgery, fractionated stereostatic radiation therapy, and intensity modulated radiosurgery.

Inova Loudoun Hospital Specific Background Information

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

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

² Ibid.

ILH is a 211-bed community hospital serving the suburbs of Loudoun County and has been serving the community since 1912. ILH is the only designated trauma center in Loudoun County. ILH provides, in addition to a variety of other services not related to this project and report, comprehensive cancer, heart and vascular services, and stroke and neurological care.

ILH has been publicly recognized for excellent care with the following accolades:

- Magnet® status from the American Nurses' Credentialing Center (ANCC) for the fourth consecutive term.
- Five out of five stars for quality by the Centers for Medicare & Medicaid Services (CMS).
- One of only 27 hospitals nationwide and the only hospital in Northern Virginia to earn straight "A's" in patient safety since the inception of the Leapfrog Hospital Safety Grade in 2012.
- Joint Commission Seal of Approval as a Primary Stroke Center
- Joint Commission Center of Excellence for Hip and Knee Replacement and Spinal Surgery.

The Inova Mary Elizabeth Miller Radiation Oncology Center-Lansdowne (Lansdowne) is on the Lansdowne campus of Inova Loudoun Hospital where the applicant states the team offers a comprehensive, team-based approach to treat all types of cancer. Lansdowne operates as part of the Inova Dwight and Martha Schar Cancer Institute. The team works in conjunction with medical and surgical oncologists, radiation therapists, oncology nurses, patient care navigators, genetic counselors, social workers, and dietitians to ensure the highest quality, multidisciplinary care for each patient. The applicant assured that individual care plans receive rigorous peer review from the entire physician team as part of the planning process. Additionally, ILH provides their cancer patients with support services, including Inova's Life with Cancer® free support and education program, yoga and fitness classes, education seminars on a variety of topics, patient and family support groups, genetic counseling, certified oncology counselors, and nutrition services. ILH's project application and their Cancer Center appear to align with Inova Health System's mission and vision:

- Mission: To provide world class healthcare – every time, every touch – to each person in every community we have the privilege to serve.
- Vision: To be among the leading health systems in the nation.

The proposed project will be completed on an established site and there will be no need for added utilities or zoning as the site is already equipped with them. Additionally, the site has ample parking adjacent to campus buildings.

HPR II/ PD 8 Population Information

Northern Virginia, HPR II/ PD 8, is a growing area of Virginia. Between 2020-2030, there is a projected 12.26% overall population growth (**Table 1**) for HPR II/ PD 8. For comparison, the entire state of Virginia is expected, for the same time frame, to grow at a rate of 5.60% (**Table 1**) and PD 8 represents 58% of the total number of people added to Virginia during the period.

Additionally, the 65+ year-old-cohort is growing at an even faster rate; this is imperative as it is projected that more than 70% of diagnosed cancers are in patients older than 65 years in the US.³ In HPR II/ PD 8, the 65+ cohort is expected to grow at a rate of 18.06% from 2020-2030, while the collective State of Virginia is only projected to grow at a rate of 27.43% for the same time frame (**Table 1**).

ILH’s primary service area is all located within Loudoun County, which is projected to experience a higher rate of population growth between 2020-2030 for both its general and 65+ cohort populations at 23.8% and 20%, respectively (**Table 1**). For the general population, Loudoun County is expected to grow at a rate 194.13% of the planning district at a whole, and 110.74% of the 65+ cohort in the planning district.

Table 1. PD 8 Population Data and Projections

HRP II/ PD 8 Population Data								
Geographic Name	2010 Census	2020 Census	%Change 2010-2020	2030 Census	% Change 2020-2030	2020 65 + Census	2030 65+ Census	% Change 65+
Alexandria City	139,993	159,309	13.8%	176,403	10.7%	3,769	3,921	4%
Arlington County	207,627	238,336	14.8%	265,794	11.5%	16,687	20,388	22.2%
Fairfax City	22,565	24,138	7%	25,358	5.1%	3,632	4,130	13.7%
Fairfax County	1,081,699	1,149,314	6.3%	1,201,420	4.5%	3,836	5,442	41.9%
Falls Church City	12,332	14,649	18.8%	16,741	14.3%	2,099	2,437	16.1%
Loudoun County	312,311	421,808	35.1%	522,015	23.8%	4,372	5,247	20%
Manassas City	37,821	42,764	13.1%	47,039	10%	1,954	2,346	20%
Manassas Park City	14,273	17,216	20.6%	19,876	15.5%	20,785	23,605	13.6%
Prince William County	402,002	482,305	20%	554,344	14.9%	3,779	4,194	11%
Total PD 8	2,230,623	2,549,839	16.61%	2,828,990	12.26%	60,913	71,710	18.06%
Virginia	8,001,024	8,646,905	8.1%	9,129,002	5.60%	1,352,448	1,723,382	27.43%

Source: Weldon-Cooper Census Data

The cancer rates for the planning district are projected to be lower than the state average; however, the cancer rates for the primary service area for ILH (Loudoun County) is projected to increase at a rate higher than that of the planning district as well as the state between the decade average rate from 2011-2020 and 2021-2030 (**Table 2**). A major factor linked to disparities in cancer rates is income; income varies in correlation with different health behaviors and education levels.⁴ According to Index Mundi, the average rate of poverty in Virginia is 10.7%. The average rate of poverty for PD 8 is 6.6%. While this may not be the only reason for the lower cancer rates in PD 8, the National

³ White MC, Holman DM, Boehm JE, Peipins LA, Grossman M, Henley SJ. Age and cancer risk: a potentially modifiable relationship. Am J Prev Med. 2014 Mar;46(3 Suppl 1):S7-15. doi: 10.1016/j.amepre.2013.10.029. PMID: 24512933; PMCID: PMC4544764.

⁴ <https://www.cancer.gov/news-events/cancer-currents-blog/2018/factors-linking-cancer-death-income-disparities>

Cancer Institute finds that higher income individuals and counties across the nation have better access to quality healthcare, make healthier lifestyle choices (such as not smoking), and have access to nutritionally substantive foods.

Table 2. Cancer Incidents and Projection Rates for HPR II/ PD 8

Geographic Name	2011-2020 Cancer Cases	2021-2030 Projected Cancer Cases	2011-2020 to 2021-2030 Projected Increase in %
Alexandria City	1,135	1,223	8.00%
Arlington County	5,270	6,424	22%
Fairfax City	1,028	1,252	22%
Fairfax County	747	8,25	10%
Falls Church City	2,310	2,501	8%
Loudoun County	2,108	2,603	23%
Manassas City	4,822	6,813	16%
Manassas Park City	1,287	1,786	13%
Prince William County	1,220	1,343	10%
Total PD 8	19,927	24,770	14.67%
Virginia	430,760	518,510	20%

Source: Weldon Cooper Center for Public Service Data

HPR II/ PD 8 Radiation Therapy Inventory and Volumes

ILH’s growth in LINAC treatment visits between 2010 and 2021 was 26.90%, while the growth for the region was an average of 9.00% (Table 3). Furthermore, ILH’s utilization based upon the State Medical Facilities Plan (SMFP) was 98% for 2021 and is projected by the applicant’s reported procedural volume for 2022 to be at 116% (Table 4). ILH’s LINAC use is significantly above those of its competitors in the region at 98% utilization in 2021 while the average for the region was 56.82% (Table 5). ILH’s projected utilization following the project completion (Table 5) would result in utilization rates more closely aligned with (although still higher than 7) their competitors (Table 5).

Inova Alexandria Hospital has 2 LINACs and has seen a decrease in 45.6% utilization between 2010-2021. Reston Hospital, 13.7 miles southeast of ILH, has seen a decrease in utilization of 26.20% between 2010-2021.

Table 3. HPR II/ PD 8 Inventory and Volumes 2010-2021

Facility/Service	# of COPN Authorized LINAC Units*	Number of Treatment Visits/Procedures				Change 2010-2021
		2010	2015	2020	2021	
Inova Alexandria Hospital	2	11,359	8,100	6,413	6,181	-45.60%
Inova Fairfax Hospital	4	25,005	15,490	20,166	25,651	2.60%
Inova Fair Oaks Hospital**	2		7,479	6,566	6,478	32.40%

<i>Inova Loudoun Hospital Center</i>	1	6,199	5,882	6,654	7,866	26.90%
Potomac Radiation Oncology Center***	1	5,369	5,557	5,551	4,931	-8.20%
UVA Cancer Center Gainesville****	2	9,381	9,762	9,084	8,540	-9.00%
Virginia Cancer Specialists	2	6,033	8,103	10,559	9,295	54.10%
Reston Hospital Center	2	6,700	5,884	4,601	4,944	-26.20%
Virginia Hospital Center	3	9,191	14,161	12,574	12,484	35.80%
Regional Total	19	79,237	80,418	82,168	86,370	9.00%

Source: Virginia Health Information (VHI) 2010-2021; HSNV Report by Dean Montgomery; COPN Inventory
 *Currently Authorized; Inova Fairfax Hospital Center also have cyberknives dedicated to providing stereostatic radiation therapy procedures. Those LINACs are used for stereostatic radiosurgery (SRS) exclusively.
 **Service opened 2014 with a LINAC transferred from Inova Fairfax Hospital
 ***Jointly owned by Sentara Northern Virginia Medical Center and Inova Health System
 ****Formerly known as Prince William-Fauquier Cancer Center

Table 4. ILH Treatment Visit/Procedures Volume and Projections

Metric	Historic Utilization					Projected Utilization if Approved	
	2018	2019	2020	2021	2022 Projected	Year 1	Year 2
LINACs	1	1	1	1	1	2	2
Radiation Therapy Treatments	5,144	6,008	6,654	7,866	9,240	10,369	10,605
SMFP Minimum Visits for Expansion	8,000	8,000	8,000	8,000	8,000	8,000	8,000
% SMFP	64%	75%	83%	98%	116%	65%	66%

Source: COPN Req. VA-8684; VHI Data

Table 5. HPR II/ PD 8 SMFP Utilization 2021

Facility/Service	# of COPN Authorized LINAC Units*	2021 # of Visits	SMFP Utilization %/Scanner
Inova Alexandria Hospital	2	6,181	38.63%
Inova Fairfax Hospital	4	25,651	80.16%
Inova Fair Oaks Hospital**	2	6,478	40.49%
<i>Inova Loudoun Hospital Center</i>	1	7,866	98.33%
Potomac Radiation Oncology Center***	1	4,931	61.64%
UVA Cancer Center Gainesville****	2	8,540	53.38%
Virginia Cancer Specialists	2	9,295	58.09%
Reston Hospital Center	2	4,944	30.90%
Virginia Hospital Center	3	12,484	52.02%
Regional Total	19	86,370	63.50%*****

Source: VHI data; HSNV Report by Dean Montgomery; COPN Inventory
 *Currently Authorized; Inova Fairfax Hospital Center also have cyberknives dedicated to providing stereostatic radiation therapy procedures. Those LINACs are used for stereostatic radiosurgery (SRS) exclusively.
 **Service opened 2014 with a LINAC transferred from Inova Fairfax Hospital
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 ****Formerly known as Prince William-Fauquier Cancer Center
 *****Calculated using the 17 LINACs that are operating with the same function as the proposed project.

Proposed Project

IHCS proposes to expand its existing radiation therapy services through the addition of one linear accelerator in existing space. The project involves the renovation of the Radiation Oncology Department (existing space) rather than new construction. The renovation will include new LED lighting utilizing recyclable and low VOC materials, as well as updated and more efficient HVAC components. Per the applicant, space design criteria and rationale for determining the size of the total facility and each department within the facility is consistent with all required and applicable building codes. The target opening date is April 1, 2024. The projected capital expense is \$6,793,811. Capital costs would be paid from internal Inova Health System funds; no outside financing will be needed.

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as “[a]ny facility licensed as a hospital, as defined in § 32.1-123...[adding] any new medical equipment for the provision of ... medical equipment that uses concentrated doses of high-energy X-rays to perform external beam radiation therapy, or proton beam 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 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.**

The applicant provided the following information regarding their public access:

ILH is well-situated with respect to public and private transportation. Public bus transportation is available near the main patient entrance, and the metro rail is available at the West Falls Church Metro Station via the Fairfax Connector and Loudoun Commuter bus services. From the Beltway (I-495), Leesburg Pike VA-7 West may be followed for approximately 20 miles to Claiborne Parkway, where hospital signs for ILH are first sited.

According to Google Maps, the West Falls Church Metro Station is approximately 26.1 miles away from ILH. **Figure 1**, below, is a map of the metrorail system in Northern Virginia found on the Loudoun County website. Google map indicates that the metrorail lines are approximately 8.3-10 miles from Inova Loudoun Hospital. There is a local bus service within Loudoun County that are \$1-2 one way. There are stops at senior centers and apartment complexes (**Figure 2**). **Figure 2** shows one of the many routes one can take using the Loudoun County transit system.

Figure 1. Northern Virginia Metrorail Map



Figure 2. Loudoun Transit to Inova Loudoun Hospital

Route 56 Rust Library/Ida Lee/County Complex—Weekdays only											
Loudoun County Government Center—Market Street	Ida Lee Recreation Center	Rust Library—Front Door	Senior Center of Leesburg*	INOVA Loudoun Hospital (Cornwall)	Loudoun County Government Center—Market Street	Gateway Drive—Bellemeade Apartments	Miller Drive—Probation & Parole Office*	Adult Detention Center*	County Complex—County Garage	Loudoun Interfaith Relief—Miller Drive*	Loudoun County Government Center—Market Street
7:00	7:06	7:08		7:16	7:22	7:28			7:45		8:00
8:00	8:06	8:08		8:16	8:22	8:28			8:45		9:00
9:00	9:06	9:08		9:16	9:22	9:28			9:45		10:00
10:00	10:06	10:08		10:16	10:22	10:28			10:45		11:00
11:00	11:06	11:08		11:16	11:22	11:28			11:45		12:00
12:00	12:06	12:08		12:16	12:22	12:28			12:45		1:00
1:00	1:06	1:08		1:16	1:22	1:28			1:45		2:00
2:00	2:06	2:08		2:16	2:22	2:28			2:45		3:00
3:00	3:06	3:08		3:16	3:22	3:28			3:45		4:00
4:00	4:06	4:08		4:16	4:22	4:28			4:45		5:00
5:00	5:06	5:08		5:16	5:22	5:28			5:45		6:00
6:00	6:06	6:08		6:18	6:22	6:28			6:45		7:00

Source: Loudoun.gov

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.

ILH provided three letters of endorsement, two of which were from other ILH departments and one from within the ILH Cancer system that included the following:

- The expansion of Radiation Oncology services will allow ILH to better serve patients in Loudoun County by allowing them to remain in their local area to receive high quality cancer care.
- The project will improve patient flow and improve overall patient satisfaction.

While there were no external community support letters, there were neither letters of opposition nor public comment presented at the public hearing. Additionally, both the HSNV’s analysis staff and Board were in agreement of the approval recommendation for this project.

(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.

As discussed above in **Background, HPR II/ PD 8 Radiation Therapy Inventory and Volumes**, HPR II, per SMFP threshold of 8,000 treatment visits / unit needed before the addition of another LINAC is needed, PD 8 is only in need of 11 LINACs. However, as also detailed above, the addition of the proposed LINAC would yield the projected utilization volumes per scanner at ILH to be much closer to the utilization of the other LINACs in the region.

The following reasonable alternatives could be considered and applicable:

1. Maintaining the status quo. While ILH is above the 8,000 procedural volume capacity, the SMFP thresholds are a minimum threshold for consideration of increasing capacity.

2. Reallocation of one LINAC from Inova Alexandria Hospital (Alexandria) in the future, when utilization increases. Alexandria has seen a decrease of 45.6% in procedural volume from 2010 to 2021 and they have two LINACs. If they only had one LINAC, their 2021 utilization would have been 77.26%. 12VAC5-230-80 section B states:
“If a facility with an institutional need to expand is part of a health system, the underutilized services at other facilities within the health system should be reallocated, when appropriate, to the facility with the institutional need to expand before additional services are approved for the applicant.”
3. Inova Fairfax Medical Campus is 32 minutes driving-time from ILH according to Google Maps. Inova Alexandria Hospital is 20 minutes driving-time from Inova Fairfax Medical Campus. Inova Fairfax could send a portion of its radiation therapy patients to Inova Alexandria Hospital, and absorb some of the ILH radiation therapy patients in order to more evenly distribute utilization.

(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.

The Health Systems Agency of Northern Virginia (HSANV) Board of Directors reviewed at its January 9, 2023, meeting the COPN application filed by Inova Loudoun Hospital (COPN Request VA-8684) that seeks authorization to add one LINAC. The Board voted unanimously (nine in favor) to recommend approval of the application.

The Board based its recommendation for approval on its review of the application, on the HSANV staff report on the proposal, on the testimony and evidence presented at the January 9, 2023, public hearing, the January 9, 2023, Board of Directors’ meeting held regarding the application, and on several basic findings and conclusions, including:

- Though demand for radiation therapy in Northern Virginia is comparatively low and there is substantial unused capacity in the region, radiation therapy service volumes at Inova Loudoun Hospital are high and increasing steadily.
- With recent increases, ILH now has the highest treatment visit per LINAC ratio in the region. The current caseload exceeds the nominal service volume planning standard of 8,000 treatment visits per LINAC annually.
- ILH qualifies for consideration to expand its radiation therapy service under the institutional need provision of the Virginia State Medical Facilities Plan (SMFP).
- Adding needed radiation oncology capacity at ILH is not likely to affect demand or caseloads at other radiation therapy services.
- The project is costly, but within the range frequently seen for comparable proposals, locally and elsewhere.

Additionally, Paul Dryer, Senior Director, Strategy & Planning, Inova Health System, Ann Miner, Senior Director, Radiation Oncology, Inova Health System and Michael Eblan, MD, Radiation Oncology Associates, Inova Loudoun Hospital stated the following for the Board:

- Demand for external beam radiation therapy at Inova Loudoun Hospital is high and increasing steadily. Recent radiation therapy service volumes, measured by patient treatment visits to the program, have been near or above the planning standard of 8,000 treatment visits per LINAC per year. Demand in 2022 was about 9,000 treatment visits.
- The treatment schedule has been expanded beyond normal operating timeframes to accommodate demand. Additional capacity is needed to permit the service to return to normal operating hours and be more convenient to patients and staff alike.
- Radiation therapy caseloads within Inova Health System radiation therapy services, though not high on average, require the LINAC capacity now available in each program. None can shift unused capacity to ILH or be restructured to serve redirected ILH patients conveniently.
- Inova Loudoun Hospital has an institutional need for additional radiation therapy treatment capacity.
- Adding linear accelerator at ILH, to meet current and projected near term demand, would not affect other programs negatively.

DCOPN concurs with and adopts the HSANV recommendation for approval the attached HSANV staff report and analysis.

(iv) Any costs and benefits of the project.

Aside from the high financial cost, the project does require additional staff (discussed further in Required Consideration 5, below) and places an additional LINAC in an area where SMFP guidelines do not determine a need for an additional LINAC. Although the projected calculated need in the PD is 18 for 2025, the utilization throughout the PD does not constitute the need for an additional LINAC. In 2021, there were a total of 86,370 treatment visits, indicating that the PD would only need 11 LINACs to be around 100% SMFP utilization; the PD has 17 LINACs at present.

The applicant provides the following benefits:

- Increasing the timeliness and access for the western portion of the HPR/PD;
- Acting in a preventative and anticipatory manner rather than prolonging action to respond to the increasing rates of cancer diagnosis in the primary service area of ILH;
- And allows for patients to continue making the choice for ILH as their radiation treatment provider by resolving their institutional need for radiation therapy services expansion in response to patient needs.

While it is evident there are patients choosing Inova for their radiation therapy needs rather than Reston Hospital Center, located only about 13.7 miles southeast (as they have had a decrease rather than the increase ILH has seen), public need must consider the access available. Relocating a LINAC from Inova Alexandria Hospital would be an option that would better distribute access and allow for patients choosing to remain within the Inova system for treatment to do so. The major equipment cost for the project is \$3,989,500; cutting this cost by relocation (and still keeping funding for updating information systems, etc.) would make the total cost closer to \$2,804,311.

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

While the average charity contribution for HPR II is 3.4% (Table 6), Inova Loudoun Hospital dedicated 4.29% of its gross patient revenue to charity care. Additionally, Inova has an Inova-wide Charity Care Condition it has pledged 3.9%, pursuant to COPN No. VA-04381 (issued April 2, 2013), as amended by the State Health Commissioner by letter dated January 4, 2016 (the Inova System-Wide Condition). Pursuant to the 2016 reconsideration, the Inova System-Wide Condition reset to 3.9% as of January 1, 2022. Provided, however, that charity care provided under the Inova System-Wide condition shall be 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.

Table 6. HPR II Charity Care Contributions 2020*

2020 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Inova Alexandria Hospital	\$949,158,182	\$57,879,875	6.10%
Inova Mount Vernon Hospital	\$499,398,426	\$29,342,493	5.88%
Inova Loudoun Hospital	\$817,869,692	\$35,123,877	4.29%
Novant Health UVA Health System Prince William Medical Center	\$530,326,336	\$21,923,014	4.13%
Inova Fairfax Hospital	\$3,855,962,450	\$147,813,100	3.83%
Sentara Northern Virginia Medical Center	\$823,831,674	\$29,925,512	3.63%
Inova Fair Oaks Hospital	\$649,476,560	\$21,302,369	3.28%
Virginia Hospital Center	\$1,491,327,243	\$29,205,595	1.96%
Novant Health UVA Health System Haymarket Medical Center	\$284,391,247	\$4,747,340	1.67%
Reston Hospital Center	\$1,535,959,085	\$19,925,030	1.30%
StoneSprings Hospital Center	\$247,806,370	\$1,302,439	0.53%
Total Facilities			11
Median			3.6%
Total \$ & Mean %	\$11,685,507,265	\$398,490,644	3.4%

Source: VHI 2020 Charity Care Contributions Data

*2020 data is the most recent data available

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

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

2. 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).

Part I. Definitions and General Information Section 80; When Institutional Expansion is Needed

12VAC5-230-80. When institutional expansion needed.

- A. Notwithstanding any other provisions of this chapter, the commissioner may grant approval for the expansion of services at an existing medical care facility in a health planning district with an excess supply of such services when the proposed expansion can be justified on the basis of a facility's need having exceeded its current service capacity to provide such service or on the geographic remoteness of the facility.**
- B. If a facility with an institutional need to expand is part of a health system, the underutilized services at other facilities within the health system should be reallocated, when appropriate, to the facility with the institutional need to expand before additional services are approved for the applicant. However, underutilized services located at a health system's geographically remote facility may be disregarded when determining institutional need for the proposed project.**
- C. This section is not applicable to nursing facilities pursuant to § [32.1-102.3:2](#) of the Code of Virginia.**
- D. Applicants shall not use this section to justify a need to establish new services.**

The applicant and the HSANV staff report concur the project being worthwhile due to an institutional specific need. ILH's utilization is far above the utilization of the other providers within the PD. ILH is the most western provider in the PD, which is more rural than the urban eastern side of the PD. However, 12VAC5-230-80 also states that underutilized services at other facilities within the health system should be reallocated before additional services are approved. There are other LINACs, Inova Alexandria Hospital's being the most appropriate, to reallocate.

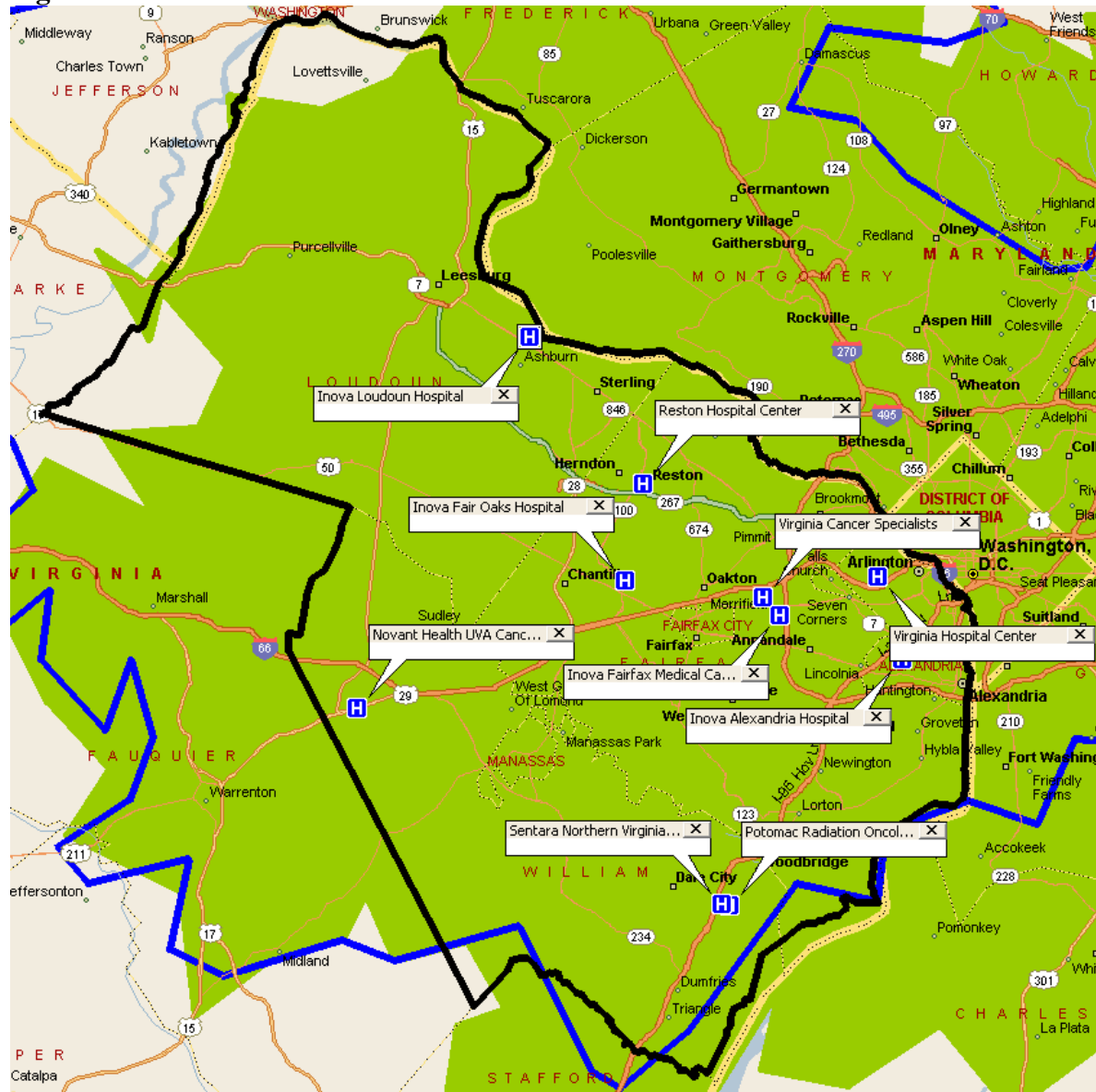
Part III. Article 1
Radiation Therapy Services
Criteria and Standards for Radiation Therapy Services

12VAC5-230-280. Travel time.

Radiation therapy services should be available within 60 minutes driving time one way under normal conditions of 95% of the population of the health planning district using a mapping software as determined by the commissioner.

The shaded green area in **Figure 3** illustrates the area where access to a LINAC is within a 60 minutes' drive of Virginia Hospital Center, while the blue line indicates a 60 minutes' drive from ILH (which has 1 LINAC service at this time); between the two locations, the entirety of the region/district is within a 60 minute drive of radiation therapy services. DCOPN chose the specific two locations to illustrate driving radius for the HPD as ILH is on the western portion of the HPR and Virginia Hospital Center is located on the eastern portion of the HPR and is also in the area with dense population. Furthermore, **Figure 3** illustrates ILH being the most western radiation therapy service provider in the HPR/ PD. While the SMFP requires radiation therapy services be available within a 60 minutes' drive of 95% of the population of the planning district, radiation therapy is usually 5 days a week for multiple weeks. The applicant argues that traveling closer to 60 minutes for services daily creates a hardship on communities that must travel further for these exhaustive, but likely lifesaving or life-prolonging services. The applicant asserts approval of this project would increase more reasonable access (less driving time) to radiation therapy services.

Figure 3. 60 Minutes' Drive Time Radius from ILH and VHC



Source: DCOPN Generated using Microsoft Streets and Trips Software

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:

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 as ILH is not requesting a new radiation therapy service. However, the following calculations are worthwhile to address possible need for services.

Calculation for subsection A:

86,370 (2021) Treatment Visits ÷ 8,000 SMFP = 10.79, or 11 LINACs
LINACs available for Radiation Therapy: 17
Calculated Surplus: 6

While the proposed LINAC will be performing at least 5,000 procedures, it will be doing so through significant reduction in use (less than 8,000 procedures) of the LINAC currently at ILH.

Calculation for subsection B:

The 2020 population of PD, according to Weldon-Cooper, was 2,549,839 and the rate of growth projected from 2020 to 2030 is 12.6%, or 1.26% per year (**Table 1**). For 2025, the projection is there will be 15,631 more individuals in the PD, for a total of 2,565,470. Weldon-Cooper projects 24,770 cancer cases between 2021-2030. The National Cancer Institute provides the cancer incidence rate for 2015-2019 as 353.6 per 100,000 people as the average for PD 8 localities.

2,565,470 x 0.003536 x 0.60
320
17.61 or 18 LINACs

For subsection C:

The applicant states they anticipate 10,605 procedures for ILH in Year 2; this is 2,605 above the 8,000 SMFP threshold. If the second LINAC were to perform an average of 4,500 procedures, the existing LINAC would be performing 6,105, or be at 76.3% SMFP utilization.

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.

To reiterate from Required Consideration 2, ii: No LINACs have performed an average of 8,000 procedures. In 2021, ILH's utilization was 98.33% of the SMFP utilization, with the next closest being Inova Fairfax Hospital with 80.16% utilization (**Table 5**). The average utilization for LINACs in the HPR is 63.50%, given 2021 VHI procedural volume.

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 provides assurances that Inova facilities will continue to participate in the Statewide Cancer Registry as required by the Code of Virginia.

12VAC5-230-320. Staffing.

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

ILH's radiation therapy services are under the direction and supervision of board-certified radiation oncologists. The radiation oncologists are authorized by the Nuclear Regulatory Commission or the Division of Radiologic Health of the Virginia Department of Health.

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.

As shown in **Figure 2**, the population center for PD 8 is east of ILH, in Central Fairfax. ILH is the most westward radiation therapy services provider and its primary service area is Loudoun County, where it is the only radiation services provider for that county. Both Western Prince William and Western Fairfax offer services more accessible for Eastern Loudoun residents, ILH is a crucial services provider for the western portion of the county/district. Approximately 13.7 miles southeast of ILH, Reston Hospital Center has 2 LINACs with a 2021 utilization of 30.90%.

Competition in the healthcare marketplace can help contain costs, improve quality, and encourage innovation.⁵ Traditional competition in healthcare can involve price, quality,

⁵ <https://www.ftc.gov/advice-guidance/competition-guidance/industry-guidance/competition-health-care-marketplace>

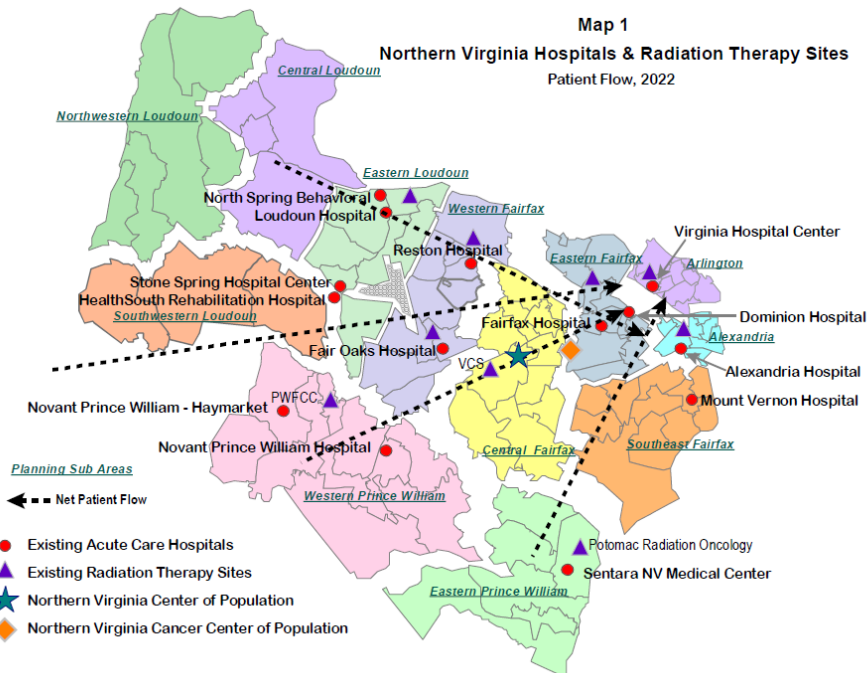
convenience, superior products or services, and technology & innovation.⁶ Competition eliminates inefficiencies that would typically yield higher production costs, ultimately transferred to the patients.

This project would not provide beneficial competition as there are substantial under-utilized resources within the PD. While the applicant's radiation therapy services are higher than others in the PD/HPR, there are locations with LINAC units that could be relocated to ILH. There is already substantial access to LINAC services within the area, with a location (of another provider-Reston Hospital Center) being 13.7 miles from the project site whose 2021 utilization was only 30.90%. Reston Hospital Center had a decline in procedural volume of -26.20% between 2010-2021 (**Table 3**).

HSANV's staff report indicates that Falls Church City's cancer incidence 5-year trend (2015-2019) is stable, while the rest of the planning district's rate is falling. The National Cancer Institute's data corroborates this information. Adding LINACs to an area with decreasing trends in cancer rates would not foster beneficial institutional competition as it would further oversaturate a market that **Table 5** illustrates is currently oversaturated.

HSANV provided **Figure 4**, detailing the patient flow towards the population center of the PD/HPR, not out towards Loudoun County.

Figure 4. Northern VA Hospitals & Radiation Therapy Sites



Source: Report for the HSANV's Board of Directors, prepared by Dean Montgomery.

⁶ Rivers PA, Glover SH. Health care competition, strategic mission, and patient satisfaction: research model and propositions. *J Health Organ Manag.* 2008;22(6):627-41. doi: 10.1108/1477260810916597. PMID: 19579575; PMCID: PMC2865678.

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.

ILH is estimated to need an additional 2.25 additional full-time employees consisting of 1 full-time radiation therapist, 1 full-time oncology patient specialist, and a 0.25 FTE medical physicist. Their recruiting initiatives are reported to include:

- They target labor pools which have historically been underutilized in the health care industry (e.g., minorities, seniors, retired military personnel, etc.) and in geographic areas well outside Northern Virginia, and expanding the pool of available workers, in each instance without draining resources from other facilities.
- Initiatives to bolster the size and quality of the health services labor pool in Northern Virginia over the long-term by promoting health care career paths among area youth, benefitting all area health care providers with a vibrant and enthusiastic labor pool.
- ILH hosts radiation therapy students for clinical rounds in the Radiation Therapy department and extends offers to new graduates for employment. The department also holds virtual job fairs for radiation therapists.

ILH's primary service area consisted of residents all living in Loudoun County. Their secondary service area includes other areas in Northern Virginia, West Virginia, and a presence from both Maryland and Delaware.

As an oncological services provider, addressing the relationship between cancer incidence rates and radiation treatment use is paramount to understanding the value of LINACs to the community. Considering breast and prostate cancers, the two most commonly diagnosed cancers in Virginia⁷, radiation therapy has an expected 95%⁸ success rate (with early detection) and a 90%⁹ success rate, respectively. While the National Cancer Institute has seen a trending decline in cancer incidence in Loudoun County, Virginia over the past five years per 100,000 people, the Northern Virginia area is projected to grow at a rate higher than the whole of the State of Virginia, meaning the number of cancer cases can increase regardless of the trending down rates per 100,000. LINACs are mostly used for external beam radiation treatment (EBRT)¹⁰; Boston Scientific reports that EBRT has an overall 98.9% survival rate at the five-year mark.¹¹ Ensuring adequate access to this therapy is imperative to positive outcomes for cancer patients.

Furthermore, as outlined above and illustrated in **Table 2**, the cancer incidence rate for Loudoun County, ILH's primary service area, is projected to continue growing at a rate higher than that of both the planning district and the state. However, there is substantial

⁷ National Cancer Institute <https://statecancerprofiles.cancer.gov/quick-profiles/index.php?statename=virginia>

⁸ <https://www.innovativecancer.com/breast-cancer/#:~:text=it's%20completely%20safe%20as%20the,has%20a%2095%25%20success%20rate>

⁹ <https://www.mskcc.org/news/what-every-man-should-know-about-radiation-therapy-prostate-cancer#:~:text=Are%20there%20side%20effects%20of,be%20achieved%20with%20either%20approach.>

¹⁰ [https://www.radiologyinfo.org/en/info/linac#:~:text=A%20medical%20linear%20accelerator%20\(LINAC\)%20is%20the%20device%20most%20commonly,region%20of%20the%20patient's%20tumor.](https://www.radiologyinfo.org/en/info/linac#:~:text=A%20medical%20linear%20accelerator%20(LINAC)%20is%20the%20device%20most%20commonly,region%20of%20the%20patient's%20tumor.)

¹¹ <https://www.spaceoar.com/clinical-outcomes-of-radiation-therapy/>

capacity still available within the PD, and within the Inova system specifically. For no costs, patients could be assigned to different hospitals, as described above, in order to redistribute utilization within the Inova system, or for a significantly reduced cost in comparison to this project, a LINAC could be reallocated. The addition of another LINAC to the PD would not increase utilization or efficiency as the average utilization per LINAC for 2021 was only 63.50%. Approval of this project would not result in an increase in utilization of radiation therapy services and would not offer an opportunity to allow other LINACs to operate to a higher capacity. Furthermore, these other services are less than the SMFP’s threshold of services being within 60 minutes of one-way travel.

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.

The estimated costs for project completion total to \$6,793,811(**Table 7**).

On January 9, 2015, HCA Health Services of Virginia, Inc. was issued COPN VA-04460 for the addition of a second linear accelerator with the authorized capital expenditure being \$5,587,216. Using the CPI Inflation Calculator¹², it is determined that \$5,587,216 had the same purchasing power in 2015 as \$7,095,503.97 in December 2022¹³. HCA’s project is comparable to the ILH’s project costs.

Table 7. Total Capital Costs Summary

Part I-Direct Construction Cost	\$2,115,000
Part II-Equipment Not Included in Construction Contract	\$4,333,138
Part III-Site Acquisition Costs	\$ -
Part IV-Site Preparation Costs	\$ 32,875
Part V-Off-Site Costs	\$ -
Part VI-Architectural and Engineering Fees	\$ 312,798
Part VII-Other Consultant Fees	\$ -
Part VIII-Taxes During Construction	\$ -
Part IX-A-HUD-232 Financing	\$ -
Part IX-B-Industrial Development Authority Revenue & General Revenue Bond Financing	\$ -
Part IX-C-Conventional Loan Financing	\$ -
Total Capital Cost	\$6,793,811

Source: COPN Req. No. VA-8684

For the first year following the project completion, the applicant projects the loss of \$131,000 from its total Radiation Oncology Services, but starting the following year, the

¹² U.S. Bureau of Labor Statistics https://www.bls.gov/data/inflation_calculator.htm

¹³ December 2022 is the most recent calculation available.

second year after project completion, the applicant projects an increase of \$73,000 in revenue over expenses (Table 8).

Table 8. Pro Forma Regarding Radiation Oncology Services

	ILH OP Radiation Oncology Baseline		Project Only (Incremental)		ILH Radiation Oncology + Incremental	
	2025	2026	2025	2026	2025	2026
Gross Patient Revenue	\$35,629,000	\$35,629,000	\$2,591,000	\$3,461,000	\$38,221,000	\$39,091,000
Deductions from Patient Revenue	\$22,401,000	\$22,401,000	\$1,629,000	\$2,176,000	\$24,030,000	\$24,577,000
Net Patient Revenue	\$13,228,000	\$13,228,000	\$962,000	\$1,285,000	\$14,190,000	\$14,513,000
Total Operating Expenses	\$6,617,000	\$6,770,000	\$1,093,000	\$1,212,000	\$7,710,000	\$7,983,000
Excess of Revenue over Expenses	\$6,611,000	\$6,458,000	\$(131,000)	\$73,000	\$6,480,000	\$6,531,000

Source: COPN Req. VA-8684 Pro Forma

The project proposes to double the quantity of LINACs in its facility and will only see an increase of revenue of 1.1% in year 2. The first-year projects a loss of 2.06%. Not adjusting for inflation, the Year 2 revenues after expenses would be 1.07% of the cost of the project.

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.

No new technology promoting quality, cost effectiveness, or both in the delivery of health services is being introduced by this project. Radiation therapy services are provided on an outpatient bases, but for this project would be in a hospital-outpatient setting. DCOPN did not identify any other discretionary factors, not discussed elsewhere in this staff analysis report, to bring to the attention of the Commissioner as may be relevant in determining a public need for the proposed project.

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 reports to host radiation therapy students for clinical rounds in the Radiation Therapy department, furthering the education and development of the future labor pool for all in Northern Virginia, and affords ILH the opportunity to extend employment offers to those students, thereby not impacting established labor pools. However, the specific schools from which the radiation therapy students originate are not presented. Furthermore, while employing newly graduated students does not detract from the current employees at other providers, it does impact other providers via those recent graduates not being able fill employment vacancies in other locations.

DCOPN Findings and Conclusions

Inova Loudoun Hospital cites an institutional need for expansion of their radiation therapy services through the addition of one linear accelerator within an existing space. While there is a calculated surplus of 6 linear accelerators in the HPR/PD, ILH is operating at a utilization over 100% for 2022 and is projected to keep increasing. All other linear accelerators in the HPR/PD are operating at a much lower utilization, where the project would yield a utilization consistent with the other linear accelerator use within the HPR/PD. Alternatively, reallocation could address the utilization discrepancies, as well as having ILH patients shift which hospital they go to for radiation therapy services. Inova Alexandria Hospital is only approximately 20 minutes away from Inova Fairfax Medical Center; Inova Fairfax Medical Center is only approximately 30 minutes away from ILH. ILH could shift some of their radiation therapy patients to Inova Fairfax, who could shift some patients closer to Inova Alexandria to their hospital. These alternatives would better utilize current available capacity, would align with the SMFP's provision regarding reallocation prior to increasing capacity in an institutional need situation, and would save a large sum of money.

Inova Loudoun Hospital is the most westward radiation therapy services provider in the HPR/PD and is experiencing a utilization rate higher than the SMFP minimum (116% utilization) for 2022, with the trend expected to increase continually. ILH is the only radiation therapy services provider with this high of utilization, and approval of the project would result in utilization rates resembling those of its competitors in the rest of the HPR/PD. While the utilization rates would be comparable to competitors, reallocation or shifting patients to appropriately utilize LINACs within the Inova system would also balance utilization without the unnecessary total capital cost being in excess of \$6 million. Furthermore, the return on the \$6,793,811 investment for Year 2 is only 1.07% of the total project cost and is only a 1.1% increase in revenues for the radiation department. The project is higher than projects that compare but could be considered reasonable if the project was necessary. Reallocation would be much more cost effective and would be a reasonable alternative if utilization as ILH were to continue to grow. Furthermore, the applicant projects a loss of \$131,000 in Year 1 and only modest gains in Year 2. This project does not appear fiscally viable.

Because of the relatively isolated location of ILH and its primary service area having no other radiation therapy services providers (with only Reston Hospital Center being 13.7 miles away from ILH on the edge of ILH's PSA) and the project completion resulting in utilization similar to those in the rest of the HPR/PD, it is unlikely that the project will have a negative effect on other

providers in the HPR/PD. The project was supported by the Board and Staff of HSANV and there is no known opposition to the project.

There is a benefit to allowing patients to continue choosing their provider of choice, but the cost of the project when there is significant unused capacity that is available to be relocated is not within the public's best interest as the costs of oversaturation in healthcare eventually fall on the patients. Based upon the SMFP threshold of 8,000 treatment visits needed per LINAC prior to authorizing additional LINAC capacity and the 17 available LINACs in the HPR/PD, there is a calculated surplus of 6 LINACs for the HPR/PD using 2021 VHI data. The applicant and the HSANV neither detailed why reallocation was not an option, nor why patients in the Eastern portion of the PSA could not travel to one of the other underutilized radiation therapy service providers within the Inova system.

DCOPN Staff Recommendations

COPN Request No. VA-8 – Inova Loudoun Hospital

The Division of Certificate of Public Need recommends the **denial** of this project for the following reasons:

1. The proposal to expand radiation therapy services through the addition of one Linear Accelerator in existing space at Inova Loudoun Hospital is not generally consistent with the applicable standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia.
2. The applicant has not demonstrated an institutional specific need for an additional linear accelerator.
3. There appears to be multiple less costly alternatives to the proposed project.
4. The capital costs of the proposed project are unreasonable.
5. The proposed project does not appear to be financially viable in either the immediate or long-term.