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March 3, 2025

TO: **Board of Directors, HSANV**
                    Interested Parties

FROM: **Dean Montgomery**

SUBJECT: **Certificate of Public Need Applications**
                    IFRC, Establish CT Service, COPN Request VA-8795

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I. Background and Summary of the Proposal

IFRC is a joint venture between Inova Health Care Services and Fairfax Radiological Consultants. It owns and operates numerous diagnostic imaging centers in the planning region, nine of which offer CT scanning. IFRC seeks COPN authorization to establish a CT scanning service at its IFRC Ballston center. The project calls for the replacement and relocation of the CT scanner now in place in the IFRC's Sterling imaging center.[1] Table 1 shows current CT capacity and recent (2023) reported CT service volumes at authorized northern Virginia services, including those of IFRC.

Estimated capital costs are $2,582,843, less than a third of which ($786,939, 30.5%) is for the scanner and related equipment. The remainder ($1,795,104) would be space acquisition, construction and related space development expenses. IFRC plans to acquire the scanner under a six-year capital lease (lease to own). Capital costs would be paid from a mix of internal funds and commercial borrowing.

IFRC justifies the proposal on the grounds that:

- The project is inventory neutral. There will be no increase in the authorized CT scanner inventory.
- The CT scanner to be replaced has reached the end of its useful life and must be replaced.
- Onsite replacement of the Sterling scanner is not an option because the lease will terminate in about a year and the site vacated.
- The replacement and relocation of the dated Sterling scanner will permit better distribution and use of IFRC diagnostic imaging services.
- Projected capital costs are within the range seen for similar projects locally and statewide.
- The project is consistent with the applicable provisions of the Virginia State Medical Facilities Plan (SMFP).

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[1] The joint venture has two members. Inova Health Care Services, a subsidiary of Inova Health System, holds a majority interest. Fairfax Radiological Consultants has a minority interest.

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If authorized on schedule, the new CT service should open in June of 2026.

II. Discussion

A. Northern Virginia CT Scanning Capacity, Use, Trends

Northern Virginia has 77 CT scanners authorized for use in diagnostic imaging.[2] They are distributed widely in hospitals, in satellite hospital emergency department services, and in nonhospital freestanding imaging centers. Distribution by setting is as follows:

- Thirty-seven are in hospitals or in buildings on a hospital campus,
- Eleven are in freestanding (satellite) hospital emergency departments,
- Six are in off-campus hospital sites with other imaging services, and
- Twenty-three are in freestanding settings not linked to a hospital.

Given the number, distribution and caseloads of local CT scanning services, most increases in capacity over the last two decades have been at hospital-based services with high service volumes and increasing demand.

CT capacity has increased by more than two-thirds (about 69%) during the last decade. In addition to the increase in the number of scanners, the replacement of older and less capable equipment with new, faster, and more capable scanners that accommodate larger numbers of patients has significantly increased the functional capacity of most CT scanning services.[3]

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[2]This count includes several scanners authorized recently that were not in service in 2023 and not included in the Virginia Health Information inventory data shown in Table 1. It excludes CT scanners dedicated to radiation therapy treatment planning and operating room use. It includes one "extra-legal" scanner, Fair Oaks Imaging Center (FOIC), which does not have, and has not sought, COPN authorization. FOIC, established by Reston Radiology Associates, the professional radiology group now known as Reston Radiology Consultants (RRC), provides professional radiology services at Reston Hospital Center. FOIC reported 2,981 scans in 2023, higher than several authorized services. Though never authorized, the service is in the Virginia Department of Health inventory and reports its service volumes as part of the annual licensing survey.

[3] Onsite replacement of existing diagnostic imaging equipment is not subject to COPN review. Replacement equipment is registered with the Virginia Department of Health. Services usually replace dated scanners with state-of-the-art equipment that serves a wider array and larger number of patients. High speed CT services are commonplace locally. They are added to the regional inventory as older equipment is retired. Replacement scanners usually incorporate technology that reduces exposure to ionizing radiation. Most CT scans in northern Virginia are obtained from such services. The IFRC proposal is consistent with this pattern. If on site replacement were an option or otherwise desired, COPN review would not be necessary.

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Table 1. Northern Virginia CT Scanner Capacity, Service Volumes 2017- 2023								
Hospitals	*Scanners*				*Year*			
	2023	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
Inova Alexandria Hospital (& Mark Imaging Center)	4	37,943	39,562	44,933	39,335	45,944	50,908	50,467
Inova Fair Oaks Hospital	3	29,752	30,608	33,010	29,171	34,828	40,468	46,144
Inova Fairfax Hospital	7	80,375	83,836	90,161	94,661	112,482	120,057	137,138
Inova Mount Vernon Hospital	2	21,000	20,347	19,763	17,186	20,977	24,116	26,164
Inova Loudoun Hospital Center (2 sites)	3	39,713	30,067	43,733	40,277	51,676	59,846	54,275
UVA Prince William Medical Center[1]	2	17,126	17,000	20,889	19,334	23,716	25,440	22,111
UVA Prince William Haymarket Center[1]	1	10,787	12,071	13,285	12,197	14,665	29,330	11,586
Reston Hospital Center	4	23,539	25,159	29,278	27,334	32,315	33,224	38,468
Sentara Northern Virginia Medical Center	3	20,332	19,982	22,073	21,728	26,169	25,673	28,970
Virginia Hospital Center	4	48,085	51,021	38,997	38,869	47,231	52,263	52,514
StoneSprings Hospital Center (SSHC)	2	5,093	5,839	6,872	6,548	8,182	8,936	9,118
Subtotal (Hospitals)	35	330,480	335,492	362,994	346,640	418,185	470,261	476,955
Free-Standing Sites								
Inova Ashburn HealthPlex	1	4,445	5,182	5,673	5,787	8,092	8,267	11,058
Fairfax ENT	1	-	-			533	622	658
Fairfax MRI & Imaging Center - Tysons	1	2,096	2,014	2,559	2,845	3,524	4,224	4,901
Fairfax Radiology Centers (Multiple Sites)	8	40,722	31,213	34,290	25,941	50,343	44,333	62,255
Fair Oaks Imaging Center[1]	1	1,717	1,933	2,060	1,955	2,605	2,864	2,981
Inova HealthPlex-Springfield	1	12,707	13,242	14,444	12,830	16,679	16,498	19,129
Inova Lorton HealthPlex	1	5,856	6,178	6,347	6,165	7,504	8,725	11,133
Inova Emergency Care Center-Fairfax	1	2,506	2,784	3,147	2,870	4,039	4,629	5,521
Insight Imaging-Arlington	1					199	1,978	3,130
Insight Imaging-Fairfax	1	3,335	3,799	3,798	4,134	4,299	3,491	4,475
IRMC Lansdowne, Sterling (Formerly RIA)	2	6,095	3,883	6,968	6,086	10,761	14,042	15,025
Kaiser Permanente (Multiple Sites)	7	30,658	32,000	29,495	29,366	35,442	60,922	79,282
LMG Imaging Center	1							708
Woodburn Nuclear Medicine (Metro Region PET)	1	-	1,423			2,815	2,763	3,187
Orthopedic Foot & Ankle Center	1	-	683	87	205	168	136	89
Sentara Advanced Imaging - Lake Ridge	1	7,252	7,449	7,779	7,576	8,941	9,232	5,406
Sentara Advanced Imaging - Lorton[2]	1	14	0	0		2		
Sentara Advanced Imaging - Springfield[3]	1	76	49	0	2	0		
Tysons Emerency (RNC)	1							2,707
UVA Outpatient Imaging-Centreville	1	131	241	844	1,359	1,249	1,306	1,444
Virginia Cancer Specialists	1							854
Washington Radiology Associates (Lakeside)	1	2,156	2,156	2,298	2,299	*	3,522	N/A
Subtotal (Free-Standing Sites)	36	119,876	114,229	119,789	109,420	157,195	187,554	233,943
Total Northern Virginia	71	450,356	450,324	482,783	456,060	575,380	657,815	710,898

Source: Virginia Hospital Licensing Reports, Virginia Health Information, 2017 - 2023

[1] Unauthorized service operated by Reston Radiology Associates.   *Not Reported

[2] Being relocated to SNVMC main campus.   [3] Being relocated in eastern Fairfax County.

Region wide, average CT service caseloads, an estimated 10,013 scans per scanner in 2023, are significantly above the _minimum_ Virginia State Medical Facilities Plan (SMFP) target level (7,400 procedures per scanner per year). There is wide caseload variation among CT programs and substantial unused capacity, principally in nonhospital freestanding services.

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The average hospital caseload was 13,627 procedures per scanner in 2023, about 84% above the nominal planning standard. Average volumes in freestanding services, 6,498 procedures per scanner in 2023, were 12% below nominal capacity. Thus, the average 2023 service volume of hospital CT services was about 2.1 times the average volume of nonhospital freestanding services, and nearly twice the Virginia SMFP minimum volume standard. Most hospital-based services routinely operate at annual service volumes much higher than the SMFP planning standard.

As these data suggest, the Virginia SMFP CT service volume standard of 7,400 scans per scanner per year is a recommended _minimum_ operating threshold, not a measure of capacity or an operating level that in and of itself justifies adding capacity.[4] Most of the unused CT scanning capacity in the region is in chronic low volume freestanding services. There is little unused capacity among hospitals and hospital-affiliated services.

Local demand for CT scanning continues to increase much faster than most other medical services, but it is worth noting that northern Virginia resident CT scanning use rates are lower than those reported nationally, in the Washington metropolitan area, and elsewhere in Virginia. The local 2023 use rate was about 15% lower than the statewide Virginia rate, and about 20% lower than the average rate elsewhere in the state (Table 2).

Table 2. Virginia CT Services
Capacity, Use, Use Rates by Planning Region, 2023

Planning Region	Scanners	Population	CT Visits	CT Procedures	Visits per Scanner	Procedures per Scanner	Average Scans per Visit	Visits per 1,000 Population	Scans per 1,000 Population
Northwestern Virginia, HPR 1	55	1,405,850	376,595	444,155	6,847	8,076	1.18	268	316
Northern Virginia, HPR 2	69	2,545,650	574,793	715,618	8,330	10,371	1.25	226	281
Southwest Virginia, HPR 3	57	1,330,048	329,851	443,866	5,787	7,787	1.35	248	334
Central Virginia, HPR 4	59	1,504,999	436,976	539,169	7,406	9,138	1.23	290	358
Eastern Virginia, HPR 5	72	1,897,072	416,780	594,665	5,789	8,259	1.43	220	313
Virginia Total	312	8,683,619	2,134,995	2,737,473	6,843	8,774	1.28	246	315
Other Virginia	243	6,137,969	1,560,202	2,021,855	6,421	8,320	1.30	254	329

Source: VHI ALSD, 2023; Population, U.S. Census Bureau

CT scanning service volumes are likely to continue to increase statewide with population growth and greater reliance on diagnostic imaging in medical practice. Regional trends and variations are longstanding and not likely to change appreciably soon.

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[4] It is worth noting that the term "procedure," as defined in the Virginia State Medical Plan (SMFP) means a study or treatment or a combination of studies and treatments identified by a distinct ICD-9 or CPT code performed in a single session on a single patient." Virginia SMFP 2011, p. 4.

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IFRC is now authorized to operate 10 CT scanners in nine locations. Two of these were approved recently and are being developed. Eight are now in service. The average use of IFRC's scanners in 2023 was 7,760 procedure per scanner, above 7,400 planning guidance and about 20% higher than the regional

freestanding CT service average. The proposal to establish a service at Ballston would coincide with the closure of the IFRC service now in Sterling (eastern Loudoun County). There would be no change in the authorized regional complement of CT scanners.

Consistency with Planning Guidelines and Principles

The Virginia State Medical Facilities Plan (SMFP) provides guidance in assessing COPN proposals seeking authorization to establish new CT services or to expand existing services: The applicable provisions, sections 12VAC-230-100 and 12VAC5-230-110, state:

> **"12VAC5-230-100. Need for new fixed site or mobile service.**
>
> A. No new fixed site or mobile CT service should be approved unless fixed site CT services in the health planning district performed an average of 7,400 procedures per existing and approved CT scanner during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of CT scanners in such health planning district.
>
> B. Existing CT scanners used solely for simulation with radiation therapy treatment shall be exempt from the utilization criteria of this article when applying for a COPN. In addition, existing CT scanners used solely for simulation with radiation therapy treatment may be disregarded in computing the average utilization of CT scanners in such health planning district.
>
> **12VAC5-230-110. Expansion of fixed site service.**
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> Proposals to expand an existing medical care facility's CT service through the addition of a CT scanner should be approved when the existing services performed an average of 7,400 procedures per scanner for the relevant reporting period. The commissioner may authorize placement of a new unit at the applicant's existing medical care facility or at a separate location within the applicant's primary service area for CT services, provided the proposed expansion is not likely to significantly reduce the utilization of existing providers in the health planning district." **Virginia State Medical Facilities Plan, P. 9.**

The IFRC proposal calls for the establishment of a new CT scanning service. Section 12VAC-230-100 applies. It is evident the IFRC proposal is consistent with this subsection if it is interpreted as applying to replacement projects.

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With the sharp reported increase in CT scanning caseloads over the last three years, application of the SMFP public need guidance, as interpreted and applied in recent years, suggests a regional need for between 78 and CT scanners.[5] Including the CT scanners authorized between 2022 and 2024, the regional complement is now 77 diagnostic scanners. This suggests that up to ten additional CT scanners may be authorized.

As emphasized by the applicant, and noted earlier, the IFRC proposal does not entail an increase in regional capacity. The IFRC Sterling scanner will be retired when IFRC Ballston opens.
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B. Cost Considerations

IFRC projects a capital outlay of $2,582,843 to establish a CT scanning service at its Ballston imaging center. Less than a third of the capital outlay would be for the scanner and associated equipment. More than two-thirds ($1.8 million) would be necessary to defray space acquisition, construction, and financing expenses. The scanner and related technology would be acquired via a six-year capital lease (lease to own).

Projected capital costs are relatively high, but there is nothing inherently problematic about the estimate. The outlay is within the range for similar projects locally and statewide.

The project is economically viable. The *pro forma* budget for the initial two years of operations indicate that the project is expected to be profitable. The projected operating return in the second operational year is projected to be about 24%. Profit margins and annual operating returns are likely to increase significantly over the useful life of the scanner, as depreciation and amortization costs decrease, and fixed costs are spread over larger service volumes. The marginal cost of providing a scan will decrease significantly as demand and service volumes increase.

As a subsidiary of Inova Health System, the applicant can be expected to follow established Inova charity care policies and practices and serve the medically indigent equitably.

C. Access Considerations

With 40 CT service delivery sites and 77 widely distributed scanners, northern Virginians have ready geographic access to CT scanning. All residents are within less than 30 minutes driving time of a service. Neither additional services nor additional scanning capacity are necessary to ensure reasonable access.

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[5] Recent reported service volume increases are unusually large. The regional compound annual growth rate (CAGR) between 2018 and 2023 was 9.6%. The reported 2023 service volume (710,898 scans) was about 32% higher than the 2019 service volume (482,783 scans), the year for the COVID-19 induced service disruptions. These are unusually large increases.

The lower need estimate (78 scanners) is based on the reported service volumes of the last five years (2018-2023). The high estimate (87 scanners) is based on the average volume over the last three years (2021-2023), the most recent years for which vetted service volume reports are available. Partial service specific caseload reports suggest that demand in 2024 has continued to increase.

The IFRC project would not add capacity. It would replace a dated scanner with a new state-of-the-art CT system and change the distribution of CT services. The proposed location, the Ballston area of Arlington County, is about twenty miles southeast of Sterling (Map 1).

Map 1
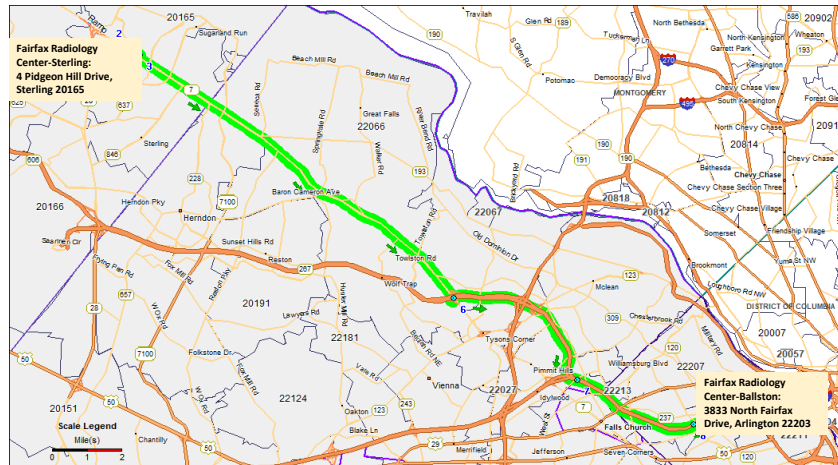
Arguably, this change would result in qualitative improvement. A new CT scanner would replace a dated scanning system. Given the number of scanners added in eastern Loudoun County and northwest Fairfax County recently, there is no indication or expectation that the closure of the Sterling service will affect negatively access to CT services among the population now served at the facility.

IFRC follows Inova Health System's charity care policies and practices. It commits to providing a reasonable amount of charity care and to serving the medically indigent equitably. There is no reason to doubt these assurances. Economic access to care is not likely to change appreciably. The _proforma_ budget assumes a charity care expense of about 5.0% of charges.

D. Health System Considerations

The Virginia SMFP public need determination formulae suggests that there is a regional need for additional CT scanning capacity. The IFRC project would replace a dated CT scanner with a new state-of-the-art scanner in a more appropriate location. Though not a quantitative increase in capacity, the projects would result in a qualitative improvement. The project is consistent with the public need determination provision of the plan (Section 12VAC5-230-100 and Section 12VAC5-230-110) as that guidance has been interpreted and applied in recent years.[6]

IFRC expects to serve 4,800 CT patients, about 65% of nominal capacity, in the second year of operations (2028). This is generally consistent with the experience of other IFRC CT services, and with the pace of service volume growth at new services. There is no indication that this would affect any service negatively.

There is no indication of likely negative health system effects from the proposal.

III. Conclusions and Alternatives for Agency Action

A. Summary Conclusions and Findings

The IRC application, and the related data and information gathered, support the following findings and conclusions.

1. The project, which calls for the replacement and relocation of a dated CT service, is inventory neutral. It does not propose a net increase in capacity but does represent a qualitative improvement in service delivery within IFRC.
2. With recent increases in CT capacity in eastern Loudoun County and northwestern Fairfax County relocating the Sterling service to Ballston (Arlington County) is not likely to reduce access to diagnostic imaging in the population now served by the Sterling scanner.
3. The applicant has acceptable charity care policies and practices.
4. The capital cost of the proposal is within the capital range commonly seen for similar projects locally and elsewhere in Virginia.
5. There is no indication of potential or likely negative health system effects.

B. Alternatives for Agency Action

1. The Health Systems Agency of Northern Virginia may recommend to the Commissioner of Health that a Certificate of Public Need authorizing the project be granted. Support for the proposal could be based on concluding that:

- The proposal, which appears to be a necessary maintenance of effort project, represents a qualitative improvement in service delivery.
- The capital outlay is within the range commonly seen for similar projects.
- There is no indication that the project is likely to result in negative health system effects.
- The proposal is consistent with the applicable provisions of the Virginia State Medical Facilities Plan.

2. The Health Systems Agency of Northern Virginia may recommend to the Commissioner of Health that a Certificate of Public Need not be granted.

An unfavorable recommendation could be based on concluding that:

- A substantial number of the recently authorized CT scanners, some within IFRC and Inova Health System subsidiaries, are not in service. Additional capital investment

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should not be authorized until these scanners are placed in service and their use assessed.

- There is no direct indication that a CT scanner is needed in Ballston and is not likely to be used efficiently.

IV.   Checklist of Mandatory Review Criteria

1. Maintain or Improve Access to Care

Northern Virginia residents have ready access to diagnostic imaging services, including CT scanning. All are within 30 minutes travel time of a CT service. With nearly two dozen service delivery sites, most residents have access to multiple CT services within a 15 to 20 minutes commute. The IFRC project is inventory neutral. It would help maintain ready access to care.

2. Needs of Residents

There is no indication that IFRC diagnostic imaging services do not try to meet the needs of the patients and communities they serve. The project described should permit it to continue to respond to the clinical needs of those it serves.

3. Consistency with Virginia State Medical Facilities Plan (SMFP)

The proposal is consistent with the Virginia SMFP public need criteria and standards and the planning principles in which the plan is grounded.

4. Beneficial Institutional Competition while Improving Access to Essential Care

The project would contribute to maintaining access to care. There is no indication or expectation that it would generate measurable price or quality competition.

5. Relationship to Existing Health Care System

IFRC is a successful operator of multiple CT scanning services locally. The project does not pose a health system conflict or problem.

6. Economic, Financial Feasibility

The capital outlay proposed is substantial but within the range commonly seen for CT scanning projects locally and statewide. It is financially feasible and is likely to be increasingly profitable over its useful life.

7. Financial, Technological Innovations

The project does not entail innovative technologies, practices or economic aspects that warrant special consideration.

8. Research, Training Contributions and Innovations

The project has no significant research or training elements that warrant special consideration.