Health Systems Agency of Northern Virginia
Board of Directors Meeting
December 16, 2024

Members Present

Ana Alvarez
Patricia Deitos, RN
Michelle Kimmel
Pamela Kincheloe, RN, Chairperson
Lydia Lawrence
Patrice Lepczyk
Anitha Raj
Douglas Samuelson
Robert Sharpe
James Smith, III MD

Staff Present

Ann McFeeley
Dean Montgomery

Guests (Partial List)

Lance Boyd, CEO, Fairfax Radiology Centers
Elizabeth Breen, Counsel, Inova Health System, IRMC
Brent Dibble, MD, Medical Director, Inova Emergency Room – Reston/Herndon, Assistant Medical Director, Inova Fairfax Emergency Department, and Physician Informatics for Emergency Medicine
Paul Dryer, Senior Director, Strategy & Planning, Inova Health System
Audrey Fisher, CEO, The Cardiovascular Group (Virginia Heart)
Jared Fisher, Director, Inova Emergency Room-Reston/Herndon
Heather Koo, Nuclear Medicine and Cardiovascular PET/CT Manager, Virginia Heart
Peter Mellette, Goodman, Allen, Donnelly, Counsel Virginia Heart
Sean McCleary, Vice President of Professional Services, Inova Health System
Patrick Oliverio, MD, Chairman, Diagnostic Radiology, Inova Fairfax Medical Campus, Medical Director, Quality, Safety and Reliability, Fairfax Radiological Consultants
Betsy Reilly, Business Analyst, JHU Healthcare
Ibrahim Saeed, MD, Virginia Heart Medical Director of Nuclear Imaging
Tom Stallings, Counsel, Reston Hospital Center
Ketan Trivedi MD, Chief Medical Officer, Virginia Heart
Spencer Wildonger, Director of Planning, Transformation, JHU Medicine
Alicia Wiygul, Director, Inova Strategic Planning, Inova Health System

I. Call to Order

Pam Kincheloe, RN, Chairperson, Health Systems Agency of Northern Virginia (HSANV), called the meeting to order at 7:30 PM. She welcomed guests and reviewed the agenda.

Kincheloe stated that, among other matters, the board would consider four certificate of public need (COPN) applications:

- **The Cardiovascular Group (d/b/a Virginia Heart), establish a cardiac PET-CT service (COPN Request VA-8782)**
- **Inova Reston MRI Center. establish a PET-CT service (COPN Request VA-8783)**
- **Inova Health Care Services, establish a CT scanning service (COPN Request VA-8784)**
- **Inova Health Care Services, expand CT scanning service at Inova Fairfax Hospital (COPN Request VA-8785)**

II. Previous Minutes

The board approved minutes of the November 11, 2024, meeting.

III. Conflict of Interest

Kincheloe followed HSANV conflict of interest procedures to determine whether any member had a conflict of interest on either of the PET-CT applications on the agenda. No conflicts were declared, alleged, or otherwise identified.

IV-A. COPN Applications: Virginia Heart, Establish cardiac PET-CT service (COPN Request VA-8782)
Inova Reston MRI Center. establish PET-CT service (COPN Request VA-8783)

1. Virginia Heart, Establish Cardiac PET-CT Service, (COPN Request VA 8782)

<u>Virginia Heart Presentation</u>

Audrey Fisher, CEO, Virginia Heart introduced herself and others present to discuss the application: Ibrahim Saeed, MD, Virginia Heart Medical Director of Nuclear Imaging and Peter Mellette, Virginia Heart COPN counsel. Among other considerations, Fisher, Saeed, and Mellette emphasized several points, including:

- Virginia Heart is the largest cardiology practice in the region, with scores of physicians and support staff, 12 practice locations, and a patient base that generates more 170,000 patient visits annually. The practice is growing rapidly.
- The cardiac PET service in Virginia Heart's Falls Church office (Telstar Court) is operating at capacity. It is unable to meet demand, referrals from within the group practice.
- Based on experience within the practice, Virginia Heart proposes adding a second PET scanning system at its Lansdowne office (Loudoun County, near Inova Loudoun Hospital).
- PET-CT scanning is the preferred diagnostic imaging option for many patients with coronary artery disease.

- The capital cost of the project is within the range commonly seen for similar projects.
- Virginia Heart projects (assumes) a charity care commitment of about 5% of projected PET-CT revenue.
- There is no indication or expectation that the project would affect demand at other local PET-CT services negatively.

Slides containing the information presented by Virginia Heart representatives in support of the application are attached (Attachment 1).

Board & Staff Questions, Discussion

In response to questions Fisher, Saeed, and Mellette stated that

- Virginia Heart has SPECT imaging systems in six of its twelve offices.
- Calcium scoring to assess cardiovascular risk entails using the CT component of the PET-CT system independent of the PET element but is inherent in diagnostic protocols and does not entail a separate charge or billable event.
- Virginia Heart will acquire the PET scanner by means of a "lease to own" contract with a commercial PET services vendor.
- There is no private equity investor involvement in the current Virginia Heart cardiac PET service, and none is contemplated for the current project.
- In-house service volumes and referral requests indicate that two PET-CT systems will not be sufficient to meet need/demand within the Virginia Heart patient base. An additional request for a third PET-CT scanner is pending.

Public Comment

There was no public comment on the application other than the letters of support submitted with the application. There is no known opposition to the project.

Applicant Final Summary

Audrey Fisher thanked the board for its attention and offered to answer any additional questions.

2. Inova Reston MRI Center Presentation, COPN Request VA-8783

Elizabeth Breen, IRMC Counsel, introduced herself and others representing the applicant: Lance Boyd, CEO, Fairfax Radiology Centers, and Patrick Oliverio, MD, IRMC and Fairfax Radiology Consultants.

Breen, Boyd, and Oliverio presented the application. They focused on the need for additional PET-CT scanning capacity to meet current and near-term projected demand among the patient population served by Inova Health System cancer services. They also noted the increasing utility and value of PET-CT imaging in diagnosing, monitoring and treating a wider array of acute care patients. The information they presented is summarized in the slides referenced during their testimony (Attachment 2). Among other considerations, they stated:

- The existing IRMC PET-CT service is used to capacity. The waiting list has grown and is increasing to unacceptable levels.

- Based on experience within the practice, IRMC proposes adding a second PET scanning system at its Centreville office (Southwest Fairfax County).
- PET-CT imaging is quickly becoming the preferred diagnostic imaging option for a wider array of acute care patients. The patient base for the service is growing rapidly.
- The capital cost of the project is substantial, but within the range commonly seen for similar projects.
- There is no indication or expectation that the project would affect the use of other local PET-CT services negatively.

Board & Staff Questions, Discussion

In response to questions Breen, Boyd, and Oliverio indicated that

- IRMC plans to acquire the PET scanner by means of a "lease to own" contract with a commercial PET services vendor.
- IRMC has extended operating hours as much as possible at its current location. The only way to respond to increasing demand effectively is to add capacity, preferably at the Centreville office.
- Demand for PET imaging is expected to continue to grow as clinical indications for its use increase.
- Given the large IRMC primary service area, a complementary PET service in Centreville is expected to improve convenient and access.

Public Comment

There was no public comment on the application other than the letters of support submitted with the application. There is no known opposition to the project.

Applicant Final Summary

Elizabeth Breen thanked the board for its consideration of the application. She offered to answer any additional questions.

Staff Recommendations, COPN Request VA-8782 & COPN Request VA-8783

Dean Montgomery referred members to the information discussed, and the conclusions reached, in the agency staff report on the applications. He noted that though technically deemed competing applications, the Virginia Heart and IRMC proposals are not competing in any practical, ordinary way. They serve distinct, separate patient populations. Based on the data and information presented in the agency staff report on the applications, on the service and practice specific service volume of each, on the testimony presented by the applicants, and on the absence of contraindicating planning guidance, Montgomery recommended approval of both applications.

Board Deliberation and Vote, COPN Request VA-8782

Douglas Samuelson offered a motion to recommend approval of the Virginia Heart application, COPN Request, VA-8782. Ana Alvarez seconded the motion. The motion passed by a vote of ten in favor (Alvarez, Deitos, Kimmel, Kincheloe, Lawrence, Lepczyk, Raj, Samuelson, Sharpe, Smith) and none opposed.

Board Deliberation and Vote, COPN Request VA-8783

Anitha Raj offered a motion to recommend approval of the IRMC application, COPN Request, VA-8783. Douglas Samuelson seconded the motion. The motion passed by a vote of ten in favor (Alvarez, Deitos, Kimmel, Kincheloe, Lawrence, Lepczyk, Raj, Samuelson, Sharpe, Smith) and none opposed.

IV-B. COPN Applications: Inova Health Care Services, establish a CT scanning service (COPN Request VA-8784)
Inova Health Care Services, expand CT scanning service at Inova Fairfax Hospital (COPN Request VA-8785)

Conflict of Interest

Kincheloe followed HSANV conflict of interest procedures to determine whether any member had a conflict of interest on either of the CT scanner applications on the agenda. No conflicts were declared, alleged, or otherwise identified.

1. Inova Health Care Services, establish a CT scanning service (COPN Request VA-8784)

Inova Health Care Services Presentation

Paul Dryer, Senior Director, Strategy & Planning, Inova Health System, introduced those representing the applicant: Brent Dibble, MD, Medical Director, Inova Emergency Room – Reston/Herndon, and Patrick Oliverio, MD, IRMC and Fairfax Radiology Consultants.

Dryer, Dibble and Oliverio presented the application. They focused on the need for additional CT scanning capacity at Inova Fairfax Hospital (IFH), within Inova Health System, and at IFH's satellite emergency service in Reston, VA. Among other considerations, they said:

- Inova Emergency Room-Reston/Herndon is the only emergency service in the region without CT scanning capability. The presentation presents a number of operating limitations and inefficiencies.
- IERRH is a satellite emergency service of Inova Fairfax Hospital, which operated from 1977 to 2013 with a CT scanner.
- IERRH's scanner was transferred to Inova's Lorton outpatient complex in 2013, where the need was greater at the time. The current proposal amounts to the reintroduction of CT capability at the Reston service.
- Demand and projected service volumes are based on recent experience at IFH's satellite emergency service in Fairfax City.
- The capital cost of the project is reasonable, within the range commonly seen locally and elsewhere.
- Reston Hospital Center's opposition to the project is misplaced. There is no indication or expectation that the service would affect any nearby CT service negatively.

Board & Staff Questions, Discussion

In response to questions Dryer, Dibble and Oliverio stated:

- Inova's Reston satellite emergency was the first of its type in the nation and remains a valued service with thousands of patient encounters, emergency and otherwise, annually.
- The CT scanner was moved to Lorton as a COPN condition in 2013.
- There is a strong need for additional CT capacity within Inova Health System, at Inova Fairfax Hospital and regionally. Reinstituting CT scanning at the Reston satellite emergency service is responsive to this need.

Public Comment

Reston Hospital Center opposes the project. Thomas Stallings, RHC COPN counsel, presented the RHC critique of the proposal. He urged HSANV to recommend denial of the application.

Paul Dryer, Senior Director, Inova Health System, presented the applicant's rebuttal to the RHC criticism. He stated the RHC opposition is inaccurate and misplaced in all respects.

The states presented by Stallings and Dryer are attached (Attachment 3 and Attachment 4).

Final Summary

Dryer thanked the board for its consideration of the proposal. He indicated that the applicant would forego a summary statement.

2. **Inova Health Care Services, expand the CT scanning service at Inova Fairfax Hospital COPN Request VA-8785)**

Inova Health Services Presentation

Alicia Wiygul, Director, Inova Strategic Planning, Inova Health System, introduced those representing Inova Fairfax Hospital: Sean McCleary, Vice President of Professional Services, Inova Health System, and Patrick Oliverio, MD, Chairman, Diagnostic Radiology, Inova Fairfax Medical Campus.

Wiygul, McCleary and Oliverio discussed Inova Fairfax Hospital (IFH) and Inova Health System CT scanning services and the reasons for adding capacity at the hospital. Among other factors, they emphasized:

- Inova Fairfax Hospital (IFH) is the busiest and most heavily used hospital in region and the Washington metropolitan area. This is reflected in the demand for diagnostic imaging services, especially CT scanning.
- IFH CT service volumes are more than twice the Virginia State Medical Facilities Plan (SMFP) service volume planning standard of 7,400 scans per scanner annually.
- In addition to regional need considerations, IFH has a facility specific need for additional CT capacity. IFH qualifies to add CT capacity under the institutional need provision of the Virginia SMFP.

- The scanner acquired would be in the hospital, increasing the inhouse CT complement to six scanners on the IFH campus.
- The capital cost, about $3.49 million, is reasonable, within the range for similar projects locally and statewide.
- Adding a CT scanner to the heavily used IFH service would not affect service volumes at other CT services.

Board & Staff Questions, Discussion

In response to the questions, Wiygul, McCleary and Oliverio stated or acknowledged:

- The scanner requested would be placed in the main Inova Fairfax Hospital CT services, increasing the total in that location to six scanners.
- Increasing reliance on CT scanning in acute care diagnosis virtually assure additional capacity will be required soon within the Inova Health System network.

Public Comment

There was no public comment other than the letters of support submitted with the application.

Final Summary

Wiygul thanked the board for its consideration of the proposal. She indicated that the applicant would forego a summary statement.

Staff Recommendations: COPN Request VA-8784 & COPN Request VA-8785

Montgomery noted that though technically characterized as competing applications, the IERH and IFH proposals are not competing in any meaningful sense. Though submitted by separate corporate entities, they are, in effect, a request to add two CT scanners to Inova Fairfax Hospital, one in the hospital's main on campus service and one at its satellite emergency service in Reston, VA. It is evident that both are needed to permit more effective and more efficient diagnostic imaging operations within Inova Health System and regionally.

Inova's Reston satellite emergency requires a CT scanner if it is to remain viable. Reston Hospital Center's opposition to the project is misplaced and inconsistent with HCA hospital (RHC and SSHC) conduct and arguments in establishing three local satellite emergency services in the last three years. Based on these considerations, on the data and information presented in the agency staff report on the applications, and on the testimony presented by the applicants, Montgomery recommended approval of both.

Board Deliberation and Vote, COPN Request VA-8784

Patrice Lepczyk offered a motion to recommend approval of the Inova application, COPN Request, VA-8784. James Smith seconded the motion. The motion passed by a vote of ten in favor (Alvarez, Deitos, Kimmel, Kincheloe, Lawrence, Lepczyk, Raj, Samuelson, Sharpe, Smith) and none opposed.

Board Deliberation and Vote, COPN Request VA-8785

Douglas Samuelson offered a motion to recommend approval of the Inova (IFH) application, COPN Request, VA-8785. Patti Deitos seconded the motion. The motion passed by a vote of ten in favor (Alvarez, Deitos, Kimmel, Kincheloe, Lawrence, Lepczyk, Raj, Samuelson, Sharpe, Smith) and none opposed.

V. Other Business

There will be no scheduled board meeting in January 2025. The HSANV Executive Committee will meeting on Monday, January 13, 2025.

VI. Adjourn

Kincheloe adjourned the meeting at 9:50 PM.

Respectfully submitted,

Dean Montgomery

Attachments (4)

Attachment 1

Virginia Heart Cardiovascular PET-CT Project Lansdowne

Audrey Fisher, MPH, FACHE Chief Executive Officer

Ibrahim Saeed, MD, Medical Director of Nuclear Imaging

Peter Mellette, Esq.

December 16, 2024

Virginia Heart Profile

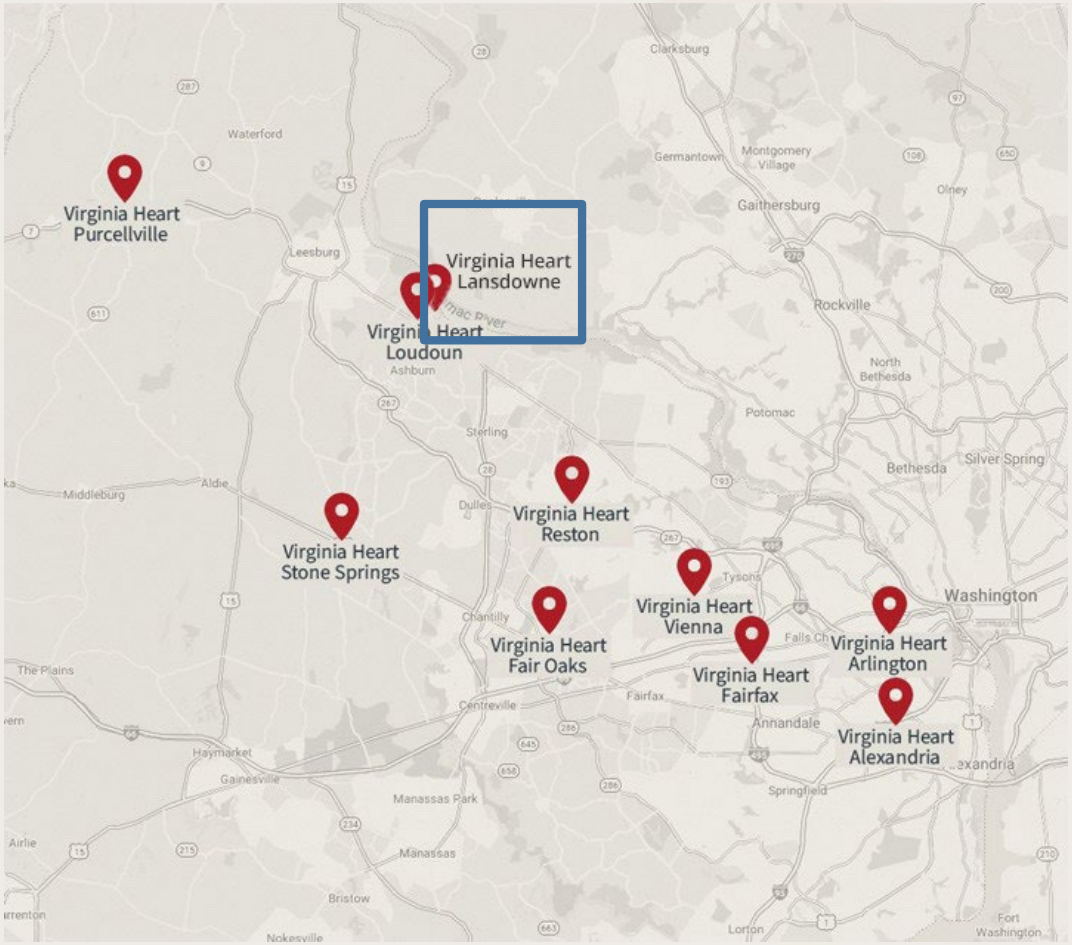
- Established in the early 1980s; Independent Practice with no affiliation or intention of Private Equity backing
- 94 providers, including 60 MDs, 34 APPs, 498 Employees
- Offering services in:
  - -General Cardiology
  - -Interventional Cardiology
  - -Structural Heart
  - -Electrophysiology
  - -Advanced Cardiovascular Imaging
  - -Advanced Heart Failure
  - -Congenital Heart
  - -Sleep Medicine
- 12 Clinic Locations throughout Northern Virginia
- Over 170,000 patient visits per year
- Serving 7 hospitals in PD8 (Inova, HCA, and VHC)
- 10-year PSA with INOVA started 1/1/2022

Patient Encounters (Annual)

	2024	2023	2022	2021	2020
Patient Encounters	171,184	162,134	157,029	151,633	139,981
Outpatient Visits	135,350	124,684	120,006	114,466	109,180
Inpatient Visits	35,834	37,450	37,023	37,167	29,801
Caths/ PCI	3,440	3,165	3,396	3,213	3,092
SPECT	5,258	6,211	5,986	5,999	5,195
PET	2,363	718	NA	NA	NA

Virginia Heart is rapidly growing due to increased demand post-pandemic and the increasing, aging population in PD 8.

Virginia Heart Locations



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Lansdowne Location: Proposed Site

Presence in PD8

- PD8 contains over 2.6 million people
  - Virginia Heart draws primarily from Arlington, Alexandria, Fairfax, and Loudoun
  - Project scope is not anticipated to include Manassas and Prince William
- Virginia Heart is the largest cardiology provider in PD8 representing 1/4 of cardiologists
- PD8 is their primary service area
  - Lansdowne site will serve Northwestern PD 8
  - Loudoun represents 31% of Virginia Heart patients

Project Rationale

- Cardiovascular PET-CT is the superior technology for non-invasive evaluation of ischemic heart disease and is rapidly replacing and/or augmenting SPECT as part of the standard in-office ancillary testing offered by ambulatory cardiology practices
- PET offers 1/6th the radiation dose on average compared to SPECT
- Diagnostic-of-choice for large BMI patients, women of child-bearing age, and the entire population for cumulative lifetime radiation exposure
- Will serve 2000+ patients not currently able to be seen at Telestar PET/CT
- Reduces retesting, unequivocal results, and unnecessary cardiac catheterization due to greater sensitivity and specificity
- Results in cost savings due to fewer unnecessary procedures
- HSANV staff recognized that “images produced with PET imaging have higher diagnostic sensitivity and specificity than…SPECT.”

Project Considerations

Why don't hospitals or free-standing radiology groups offer Cardiovascular PET-CTs on existing machines?

- Onerous pre-authorization processes- often require peer-to-peer reviews with cardiologists.
- Radioactive tracers are specific to Cardiac
  - $500K+ a year
  - Require enough volume to cover the cost
  - Difficult to achieve if machines are not dedicated to Cardiac use
- Typically require readings by trained cardiologists & personnel specifically trained in Cardiovascular PET-CT
- Require cardiac specific software
- Oncology studies:
  - Have significantly fewer barriers for entry and use
  - Have lower operating & isotope costs
  - Do not require cardiologists & cardiac-trained staff to supervise

What is PET/CT?

- **P**ositron **E**mission **T**omography/**C**omputed **T**omography
- What is it not?
- Why is it better than SPECT?

Myocardial Perfusion Imaging (MPI)

- Cardiology practices offer a wide array of in-office testing for patients that enable them to diagnosis and treat cardiovascular disease. These ancillary services are typically used specifically for a single practice to maintain convenience and continuity of care for patients.
- MPI testing is a fundamental part of in-office testing that allows providers to evaluate the health of heart muscle and the health of the arteries that supply blood to the heart itself. If the heart muscle is damaged and/or the arteries are clogged, patients are treated medically or sent for surgical interventions.
- SPECT has been the traditional long-standing modality for MPI testing because it is non-invasive and can be done in a medical office, but it does not have a high degree of accuracy. When a SPECT test does not provide definitive results, patients are referred to the hospital to have an invasive cardiac catheterization which allows for more definitive diagnosis although it is more costly and carries potential complications.

Myocardial Perfusion Imaging (MPI)

- PET is a technology that has been used for decades in the hospital setting, primarily for other specialties like oncology. It is not efficient nor feasible for most hospitals to offer PET for cardiology.
- PET is much higher quality and more definitive, but there have been significant hurdles in deploying it in ambulatory cardiology practices:
  - Requires a special radioactive isotope (Rb-82) that has a short half-life (approximately 75 seconds), so it requires an on-site generator that has a fixed expense and a fixed amount of isotope.
  - Requires capital expenditures that are often prohibitive for medical practices.

Myocardial Perfusion Imaging (MPI)

- In recent years, some things have changed that have made PET more feasible and accessible to cardiology practices:
  - New sources of Rb-82 have been identified, so there is no longer a single supplier in the world.
  - Third-party vendors have come up with creative ways of supplying Rb-82 to cardiology practices such as sharing generators between practices so that the fixed cost and volume per generator can be shared amongst multiple practices.
  - Equipment vendors are offering flexible financing options like leasing and leasing-to-own, thus reducing the upfront capital burden of acquiring a PET scanner.
  - As more cardiologists have been exposed to the superior quality of PET, there has been increasing desire for rapid diffusion of this technology.
  - As PET has started to be more utilized in ambulatory cardiology, national associations such the American College of Cardiology and the American Society of Nuclear Medicine have endorsed it as the preferred, gold-standard for MPI testing.

PET vs SPECT

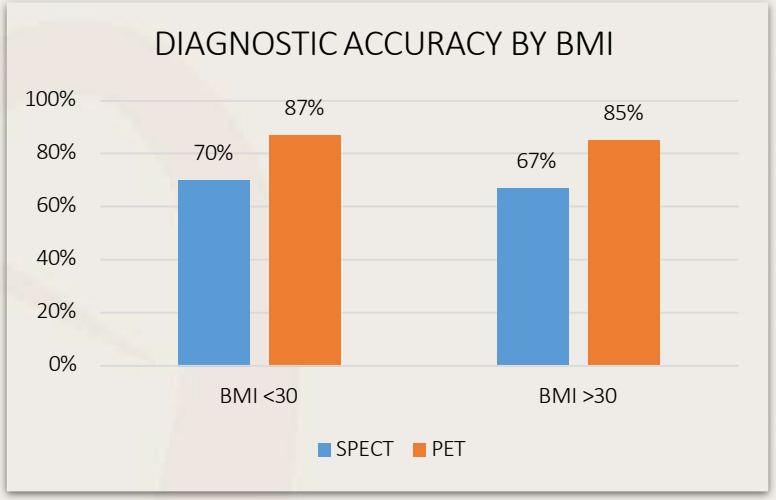
Per literature, PET scanning as 1st line test may decrease use of unnecessary cardiac catheterizations by more than 50% secondary to improved accuracy:

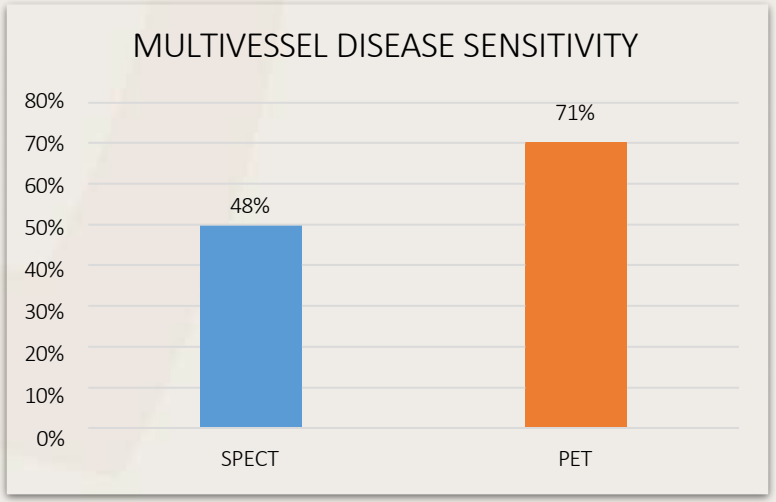
- Heart attacks & unnecessary cardiac catheterizations are significantly lower after 1 year in patients managed by PET
- Decreased number of invasive procedures: cardiac catheterization, angioplasty, stenting, & open-heart surgery lower in patients managed by PET
- Average cost to manage a patient with coronary artery disease was 25% lower in PET group

M. Merhige et. al, IMPACT OF PET MPI ON CAD MANAGEMENTJ Nucl Med 2007; 48:1069–1076

Important Properties of Cardiovascular PET/CT

- High diagnostic accuracy
- Consistently high-quality images
- Low radiation exposure
- Shorter testing time
- Strong prognostic power
- Quantification of myocardial blood flow
- Vulnerable populations benefit most:
  - Obese
  - Young with known CAD
  - Women
  - Kidney failure
  - Frail
  - High-risk patients where you CANNOT be wrong





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Journal of Nuclear Medicine 2016;57(10):1-3

Bateman TM., et al. Diagnostic accuracy of rest/stress ECG-gated Rb-82 myocardial perfusion PET: Comparison with ECG-gated Tc-99m sestamibi SPECT. *Journal of Nuclear Cardiology* 2006; 1: 24-33

SPECT vs PET vs PET-CT Pros and Cons

	SPECT	PET	PET-CT
Radiation Exposure	Moderate	**Low**	**Low**
Anatomical Accuracy	Moderate	Moderate	**Excellent**
Image Quality	Suboptimal	Better	**Optimal**
Spatial Resolution	Fair	Better	**Optimal**
Quantitative Estimate of Blood Flow	Not Available	**Yes**	**Yes**
Diagnostic Accuracy	Good	Better	**Optimal**
Quality in High BMI or Central Obesity	Poor	Good	**Optimal**
Calcium Scoring for Early Detection	Not Available	Not Available	**Yes**
Prognostic Value of Normal Results	Good	Very Good	**Excellent**
Equipment Expense	**Moderate**	High	Highest

Why do we *NEED* this?

- Falls Church PET/CT scanner is beyond maximum capacity
- Authorized in 2022 and implemented in 2023, it will perform ~2400 scans in 2024, despite initial projection of 1200/year
- Restricted primarily to Medicare Fee for Service (35% of patients) while establishing contracts with private payors
- As the HSANV Staff Summary noted, “most commercial medical insurance carriers historically did not cover PET imaging. Now, studies show greater sensitivity and specificity, and commercial carriers are beginning to initiate coverage”
- Even while restricted to 35% of Virginia Heart’s patients, over 3600 PET/CTs have been ordered in 2024

Why do we *NEED* this?

- We have recently established contracts with 2 major private payors and are in negotiations with 2 others which will open this up to the other 65% of patients
- Minimum demand is projected to be 10K scans per year when it is opened to private payors
- Total demand is difficult to quantify because many patients who are not candidates for SPECT (morbidly obese, claustrophobia, mobility) are candidates for PET, so there is **unmet demand**

Patient Encounters (Annual)

	2024	2023	2022	2021	2020
Patient Encounters	171,184	162,134	157,029	151,633	139,981
Outpatient Visits	135,350	124,684	120,006	114,466	109,180
Inpatient Visits	35,834	37,450	37,023	37,167	29,801
Caths/ PCI	3,440	3,165	3,396	3,213	3,092
SPECT	5,258	6,211	5,986	5,999	5,195
PET	2,363	718	NA	NA	NA

Virginia Heart is rapidly growing due to increased demand post-pandemic and the increasing, aging population in PD 8.

Why do we *NEED* this in Loudoun?

- Demand for cardiology services increasing significantly since the pandemic, and with the growing & aging population
- Virginia Heart has been adding providers and increasing in new patients significantly which equates to increasing demand for PET
- Many patients are unable or unwilling to travel to Falls Church
- Establishing new service rather than expanding existing service should improve access (HSANV staff summary)
- ~30% of Virginia Heart patients are in Loudoun - having PET in this location makes it convenient & accessible to a large portion of patients

Virginia Heart PET Results

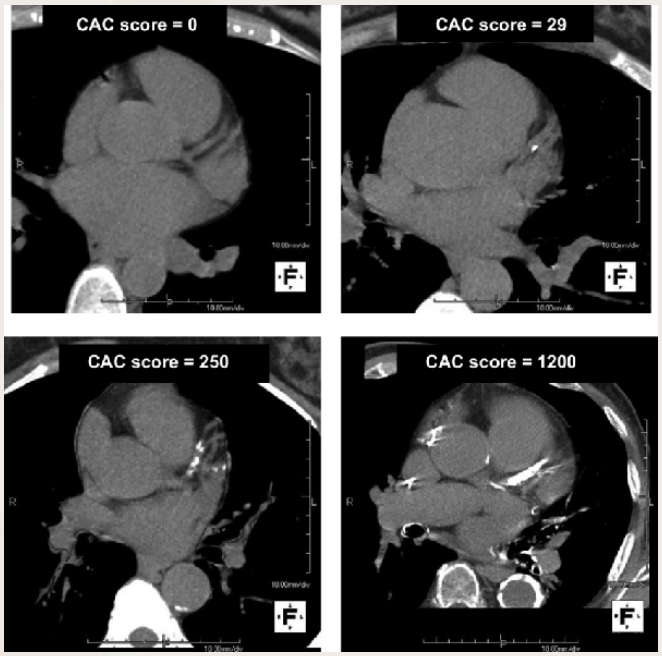
Virginia Heart SPECT vs PET/CT Patient Results			
	Referred for Cardiac Catheterization	Required Intervention (Stent/Surgery)	False Positive Rate
SPECT Jan-Dec 2022 (N=5,986)	5% (292)	43% (126)	57%
PET/CT Aug 2023-July 2024 (N=2,180)	7% (157)	75% (117)	25%*,**

*Not all “false positives – often identified true cardiac disease that required other treatment like medical management

**This also reflects an older population that was tested

Coronary Artery Calcium Scoring

- Calcium is found in all levels of atherosclerotic plaque
- Found to be incrementally MORE predictive of coronary artery disease than the classic risk factors of:
  - Diabetes mellitus
  - Hypertension
  - Family History
  - Hyperlipidemia
  - Smoking
- Virginia Heart plans to offer a community sliding scale payment to benefit lower socioeconomic groups (who have been historically a higher risk population.)



Charity Care & Community Benefit

- Proactive outreach for calcium scoring at health fairs and community events to underserved communities
- Sliding scale fee for services
- Virginia Heart Community Foundation
- Community Health Fairs
- Charity Care Policy
- HSANV staff summary recognized Virginia Heart's history of service to medically indigent patients

Collaboration with Inova

- January 1, 2022, Inova and Virginia Heart entered into a 10-year agreement.
- Virginia Heart's PET-CT service is a collaborative program with Inova cardiologists (combined total of over 50% of the cardiologists in PD8) to meet community need.
- This allows for greater access to this technology throughout the PD8 community.

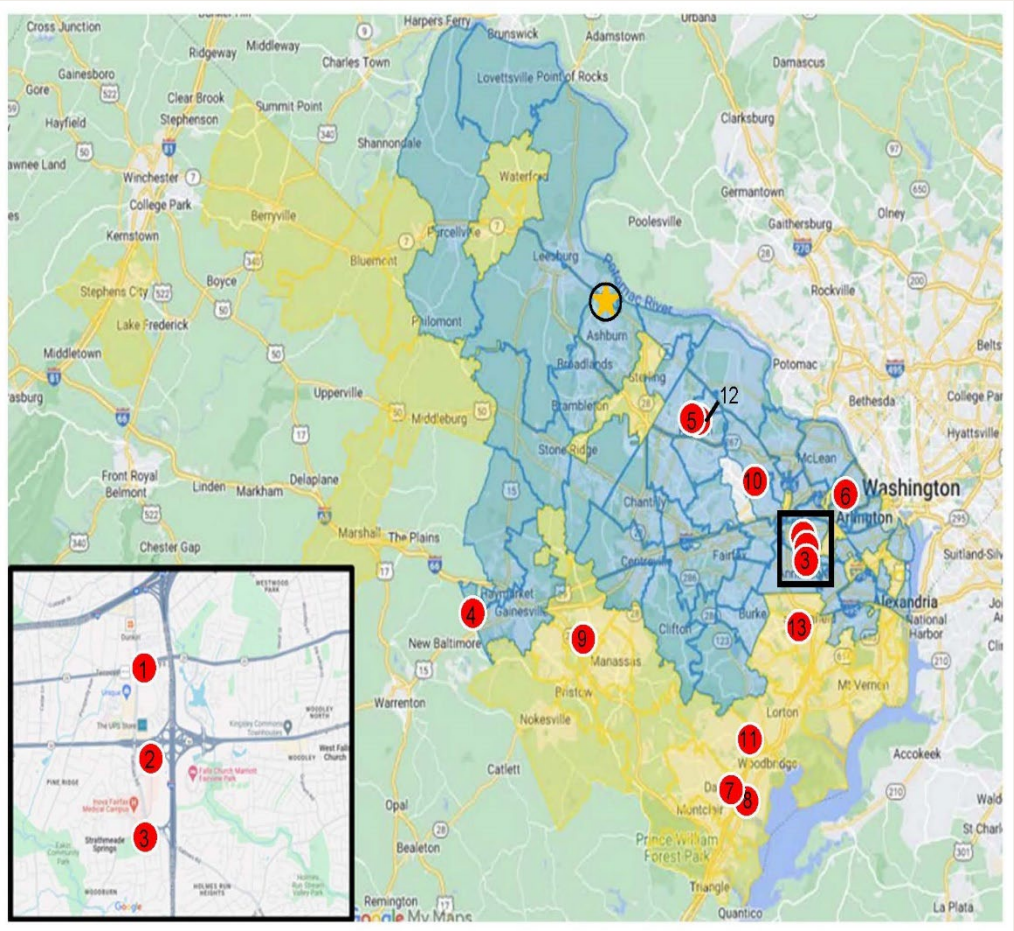
Summary

Cardiovascular PET-CT is a much-needed service that remains unmet in PD8.

- Superior, first-line diagnostic tool for detecting ischemic heart disease
- Safer, higher quality, and more accurate than traditional SPECT
- Experience to date suggests “greater sensitivity and specificity are of substantial clinical value in reducing false positive and false negative test results” (HSANV staff summary), reducing inappropriate invasive procedures
- Identifies more cardiac disease so patients can be treated earlier before more serious issues arise
- Helps to reduce the overall cost of care for patients with ischemic cardiac disease

Health Planning Considerations

1. **The proposed project will provide access to Cardiovascular PET/CT Services in PD 8.**
   - Primary service area of almost 2 million people and over 2.6 million total in PD8
   - Only ¼ of Virginia Heart's eligible patients have access to PET/CT now
   - SPECT is not less costly & more effective alternative – PET/CT provides clearer, more accurate images and additional diagnostic capabilities
   - Cardiovascular PET/CT reduces follow-up testing, lowers overall costs, and minimizes radiation exposure
   - Per HSANV staff, "developing a Virginia Heart cardiac PET imaging service in Lansdowne has the potential to improve access by adding the service option in Loudoun and western Fairfax counties."



Virginia Heart Primary and Secondary Service Areas

2. The proposed project will help meet the cardiovascular testing needs of PD 8 residents.

- *There is public support for Virginia Heart's PET/CT project - Sample comments*
  - "Cardiac PET/CT services are the best way to diagnose and identify these at-risk populations and provide equitable, timely, and accurate care that reduces the need for downstream testing and reduces costs…There is currently no option available in the westernmost area of PD 8 to refer my patients who need PET/CT scans." – Dr. Sarin, Chief of Adult Cardiac Surgery at Inova Heart and Vascular Surgery

  - "PET/CT is far more sensitive than SPECT and is more useful in diagnosing heart disease. Simple PET can identify some abnormalities, but the lack of CT does not allow accurate co-localization of infections or quantify coronary calcium." – Virginia Heart physician

  - "In the past 10 years, PET/CT imaging has been discussed as a means of improving quality and reducing unnecessary procedures for cardiac patients." – Dr. Sasson, EVP of MedAxiom

  - "The addition of another PET/CT scanner at Virginia Heart would ensure our patients have the best possible outcomes and quality of life." – Virginia Heart physician

3. The Virginia Heart PET/CT project is consistent with SMFP Guiding Principles

- *The project will not create excess capacity or underutilized medical facilities*
  - Virginia Heart's 2024 SPECT and PET/CT utilization of 8193 annual MPI procedures supports at least 3 cardiovascular PET/CTs at 2,000+ annual procedures each; over 100 PET/CT orders/month not met on Medicare FFS population; providers currently in Loudoun County Virginia Heart offices not referring other commercial patients to PET
  - Virginia Heart's Lansdowne location would be located in a different primary service area than existing cardiac PET/CT projects
- *The project will improve the geographical distribution of cardiovascular PET/CT services and promote the availability and accessibility of proven technologies.*
  - Existing PET/CT scanners limited to oncology, neurology, and urology uses; no indication of cardiac PET/CT use
  - Cardiovascular PET/CT is the first-line, preferred test for patients
- *The project will promote the development of services by every person who needs them without respect of ability to pay.*
  - Shown willingness to serve equitably and annual charity care provision per HSANV Staff
- *The project will not result in the proliferation of services that would undermine existing community providers*
  - Scanner is dedicated as proposed to cardiovascular PET/CT and will not duplicate currently available PD 8 PET/CT services; protocols limit unnecessary use

4. The project is consistent with specific SMFP provisions

12VAC5-230-200 Travel Time:

- No cardiovascular PET/CT service currently available in Loudoun County
- Lansdowne location would improve existing patient population access to PET/CT within Virginia Heart practice

12VAC5-230-210 Need for New Fixed Site Service:

- As HSANV staff note, "The Virginia SMFP language reflects the expectation that PET service development proposals are likely to be designed and structured to serve cancer patients."
- "It is recognized that the [PET] service volume planning standard is dated and inapplicable."
- With one exception, currently reported PET/CT volume to VHI reflects utilization in oncology, neurology, and urology patients – not cardiovascular patients
- Comparable SPECT data from VHI Reports and Virginia Heart's internal data shows sufficient utilization to support a dedicated Cardiovascular PET/CT in Loudoun County
- Cardiovascular PET/CT is the preferred diagnostic tool

12VAC5-230-240 Staffing: Dr. Ibrahim Saeed will serve as the nuclear medicine director; Trained on delivery/interpretation of Cardiovascular PET/CT

12VAC5-230-50 Project Costs: Projected capital costs of $3,816,902 are consistent with or lower than the costs and expenses of similar projects

5. The Virginia Heart PET/CT proposal is consistent with other planning criteria

a. *No negative impact on existing facilities*

- No dedicated cardiovascular PET/CT services exist in Loudoun County
- Virginia Heart's current volume of over 8,000 MPIs/year on less than all patients supports project
- Per HSANV staff, "no indication or reason to believe that … project would affect demand at competing PET services." Instead, it "would help maintain access to heavily used services."

b. *The project is feasible as proposed*

- Development and operating costs are reasonable [per HSANV staff]
- Renovation of existing leased space, with limited construction costs
- Minimal human resources/staffing necessary

c. *The project offers significant improvements and innovations in delivery of cardiology care*

- *Improvements*: Per HSANV staff, "Higher PET sensitivity, widely applied, should reduce the number of false negative studies, permitting those needing specific cardiovascular treatment to obtain it sooner. Greater specificity should reduce the number of false positive studies and, thereby, reduce the number of unnecessary diagnostic cardiovascular interventions. e.g., cardiac catheterization." Further, "cardiac PET imaging results in a clinically meaningful improvement in cardiovascular patient diagnosis and treatment. If [Virginia Heart's data and] findings prove indicative of the potential value of cardiac PET imaging generally, the region will be well served by the ongoing, unimpeded shift from SPECT to cardiac PET imaging."
- *Innovations*: Eliminates further downstream testing and reduces costs and risks associated with unnecessary cardiac catheterizations

Virginia Heart's Commitment

- Excellence in Cardiovascular Care is our culture in all that we do
- Nationally and Internationally recognized practice
- Founding Member of MedAxiom
- To this end, we are pursuing the highest quality PET/CT available on the market

Thank You!

Attachment 2

IRMC, LLC
COPN Request VA-8783
Establish a PET-CT Service
COPN Hearing Handouts

Health Systems Agency of Northern Virginia
Board of Directors Meeting
December 16, 2024

FAIRFAX RADIOLOGY CENTERS
An Inova partnership

Summary of Key Points

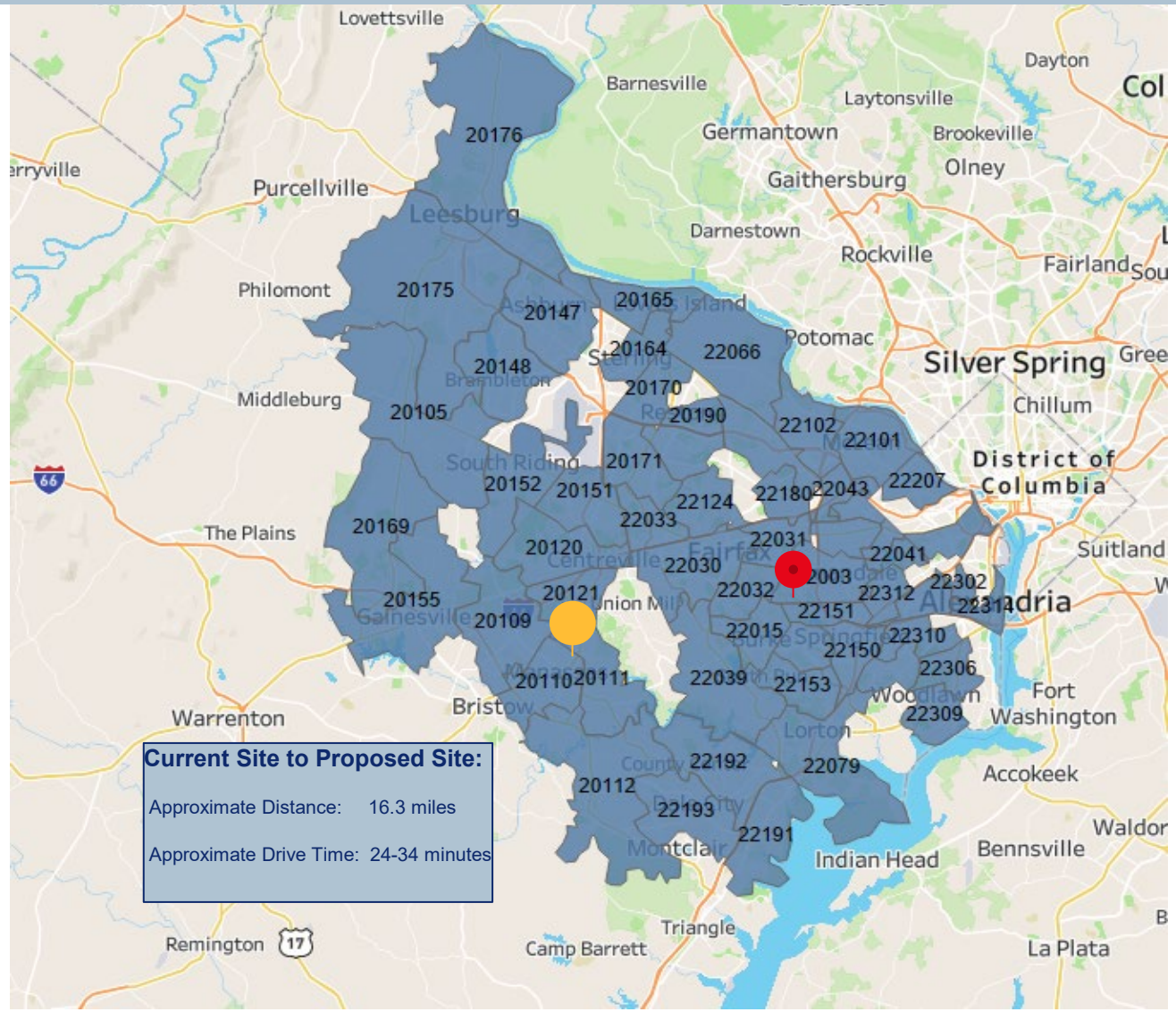
- IRMC's current Fairfax-based PET/CT facility is at capacity
  - Current wait time to appointment is 24 days. Operating hours are Monday through Friday from 7 AM to 6:30 PM, with 20 (non-cardiac only) slots max/day.
  - 2023 PET procedures totaled 3,893 while November 2024 YTD annualized totaled 4,174 (7.2% growth). This was facilitated by extending hours and optimizing workflow.
  - Extending hours any further is problematic due to the limited shelf life of the isotope and inability to access radiopharmaceuticals after delivery of the last dose at 2 PM each day. Similarly there is limited availability of radiopharmaceuticals on weekends.
  - The expected annual growth rate for outpatient PET/CT in PD 8 is approximately 4.2%[1] while PD 8 population growth is at 1.3%[2]. Clinical applications for PET/CT continue to grow (i.e., brain/Alzheimer's).
- IRMC would like to introduce a PET service at the Centreville facility 16 miles from the current one to serve existing patients
  - Will reduce wait times and improve the patient experience by allowing the next phase of care to proceed sooner and provide a more convenient location for patients located in the western part of PD8.
  - Capital cost is $5.2M, 58% of which is for the PET/CT unit. If approved, project is planned for completion by April 2026.

Data sources: [1]Healthcare Advisory Board Imaging Market [2] Weldon Cooper

Note: IRMC complies with the charity policies of its majority shareholder (Inova).

Current Location/Primary Service Area and VA-8783 Proposed Location

The PET/CT would be placed at an existing IRMC facility in Centreville 16 miles west of the current IRMC site in Fairfax.



The proposed location is within IRMC's PET/CT Primary Service Area (top 75% Zip Codes by patient origin)

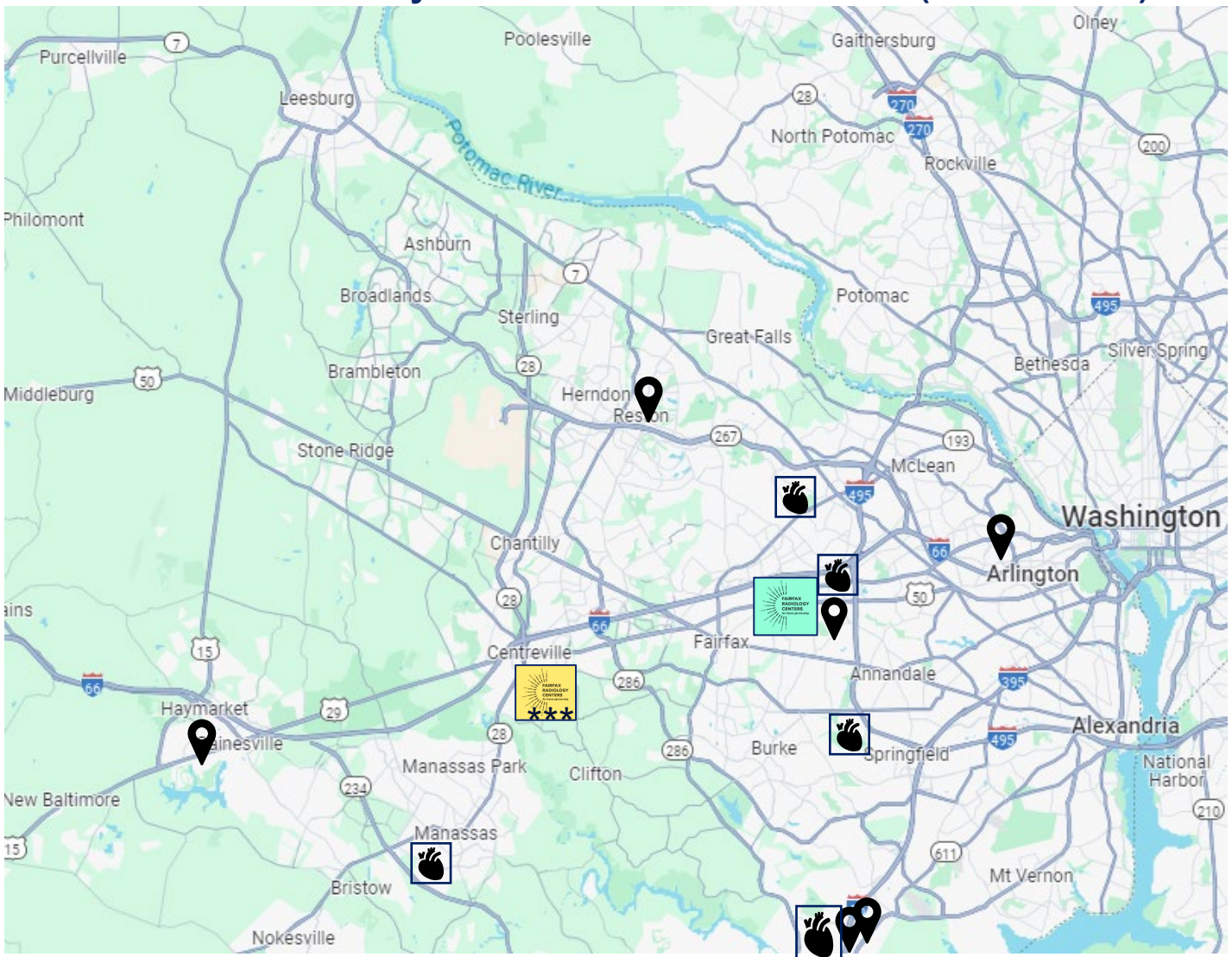
FRC IRMC Current PET Location

FRC IRMC Proposed 2nd PET Location

Zip	County	City	SA
22003	Fairfax County	Annandale	PSA
22030	Fairfax City County	Fairfax	PSA
22015	Fairfax County	Burke	PSA
20147	Loudoun County	Ashburn	PSA
20120	Fairfax County	Centreville	PSA
22032	Fairfax County	Fairfax	PSA
22150	Fairfax County	Springfield	PSA
22304	Alexandria City County	Alexandria	PSA
20148	Loudoun County	Ashburn	PSA
22033	Fairfax County	Fairfax	PSA
22192	Prince William County	Woodbridge	PSA
22193	Prince William County	Woodbridge	PSA
22314	Alexandria City County	Alexandria	PSA
22031	Fairfax County	Fairfax	PSA
22101	Fairfax County	McLean	PSA
22042	Fairfax County	Falls Church	PSA
22151	Fairfax County	Springfield	PSA
20151	Fairfax County	Chantilly	PSA
22102	Fairfax County	McLean	PSA
20170	Fairfax County	Herndon	PSA
20155	Prince William County	Gainesville	PSA
22182	Fairfax County	Vienna	PSA
20176	Loudoun County	Leesburg	PSA
22309	Fairfax County	Alexandria	PSA
22180	Fairfax County	Vienna	PSA
22310	Fairfax County	Alexandria	PSA
22079	Fairfax County	Lorton	PSA
22312	Fairfax County	Alexandria	PSA
22153	Fairfax County	Springfield	PSA
20191	Fairfax County	Reston	PSA
22152	Fairfax County	Springfield	PSA
20165	Loudoun County	Sterling	PSA
22066	Fairfax County	Great Falls	PSA
22191	Prince William County	Woodbridge	PSA
20110	Manassas City County	Manassas	PSA
20111	Prince William County	Manassas	PSA
20171	Fairfax County	Herndon	PSA
22043	Fairfax County	Falls Church	PSA
22207	Arlington County	Arlington	PSA
22124	Fairfax County	Oakton	PSA
20152	Loudoun County	Chantilly	PSA
22315	Fairfax County	Alexandria	PSA
20169	Prince William County	Haymarket	PSA
20121	Fairfax County	Centreville	PSA
20175	Loudoun County	Leesburg	PSA
22041	Fairfax County	Falls Church	PSA
22039	Fairfax County	Fairfax Station	PSA
20109	Prince William County	Manassas	PSA
22046	Falls Church City County	Falls Church	PSA
20164	Loudoun County	Sterling	PSA
22204	Arlington County	Arlington	PSA
22302	Alexandria City County	Alexandria	PSA
22306	Fairfax County	Alexandria	PSA
20105	Loudoun County	Aldie	PSA
20190	Fairfax County	Reston	PSA
20112	Prince William County	Manassas	PSA
22044	Fairfax County	Falls Church	PSA
22181	Fairfax County	Vienna	PSA

Current PD 8 Authorized PET Services and VA-8783 Proposed Location

The proposed PET/CT in Centreville would be placed at an existing IRMC facility 16 miles west of the current IRMC site in Fairfax and 16 miles away from the next closest fixed (non-cardiac) competitor site.



*** = Proposed Location

Icon	Location	Type	Unit
	Carient Heart & Vascular	Fixed, Cardiac	2
	Virginia Heart **	Fixed, Cardiac	1
	Amelia Heart and Vascular**	Fixed	1
	Fairfax PET/CT Imaging Center	Fixed	1
	Kaiser Permanente Woodbridge Imaging Center	Fixed	1
	Metro Region PET Center	Fixed	2
	Virginia Hospital Center	Fixed	1
	UVA Health Gainesville	Mobile	1
	PET of Reston	Fixed	1
	Sentara Northern Virginia Medical Center	Mobile	1

* NOVA Cardiovascular Care obtained a cardiac PET/CT for location in Woodbridge in 2023 **

** Not active in 2022 VHI Reporting

McGuireWoods

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December 12, 2024

Karen Shelton, MD FACOG
State Health Commissioner
Virginia Department of Health
109 Governor Street, 13th Floor
Richmond, VA 23219

Re: COPN Request No. VA-8784
Inova Health Care Services, d/b/a Inova Fairfax Hospital
Establish a Medical Care Facility for CT Imaging with One CT Scanner at the Inova Emergency Room – Reston/Herndon
Planning District 8

Dear Commissioner Shelton:

I am writing to express Reston Hospital Center's opposition to COPN Request No. VA-8784 filed by Inova Health Care Services to establish CT imaging at Inova Emergency Room – Reston/Herndon ("Inova ER Reston").

Data provided in Inova's application contradict Inova's claim that its project will not impact any other provider. To the contrary, the project will clearly adversely impact Reston Hospital Center, which is located only 0.6 miles away.

Section III.A of Inova's application states that 567 patients were transferred from Inova ER Reston during a recent 12-month period, "mostly due to the need for advanced imaging, in particular CTs":

> From September 1, 2023 though September 1, 2024, 567 patients were transferred out of the Inova Emergency Room – Reston/Herndon, mostly due to the need for advanced imaging, in particular CTs that can initiate stroke activation protocols.[1]

Inova does not state how many of the 567 transfers required a CT scan, only that "most" needed some type of advanced imaging, "in particular" CT. Clearly, the number of transfers requiring CT imaging is less than 567. In the absence of Inova sharing the

[1] Inova ER Reston COPN application at III.A (unnumbered 13th page of application).

precise number of patients that needed CT imaging, I will assume for purposes of this letter that the number is approximately 400.[2]

In Section III.G,[3] Inova projects 4,432 CT scans in Year 2, 3,427 of which will be ER scans.

Inova Emergency Room – Reston/Herndon

	Projected Year 1+2	
	2026	2027
# CT Scanners	1	1
# CT Scans	4,053	4,432
CT Scans - Emergency	3,383	3,427
CT Scans - Scheduled	670	1,005
% of SMFP	55%	60%

If Inova ER Reston transfers approximately 400 ED patients for a CT scan annually today, that means that approximately 3,000 of the patients projected to receive an ED CT scan at Inova ER Reston are not seen there today. Where will these patients come from? Almost certainly from nearby Reston Hospital Center.[4]

Inova claims its project is consistent with 12 VAC 5-230-110. However, -110 expressly excludes from authorization thereunder any project "likely to significantly reduce the utilization of existing providers in the health planning district." Because Inova ER Reston projects to perform approximately 3,000 ED CT scans annually that are not currently transferred out of the facility today, Inova's proposed project is most-certainly "likely to significantly reduce the utilization of" Reston Hospital Center and, therefore, cannot be approved under -110.[5]

The likely adverse impact on Reston Hospital Center is particularly concerning given Inova's status as PD 8's dominant provider. As the Commissioner and DCOPN have repeatedly noted, roughly half of all CT scanners in PD 8 are owned by, or in

[2] The analysis is the same – and reaches the same conclusion – no matter what percentage of the 567 total transfers required CT imaging.

[3] Inova ER Reston COPN application at III.G (unnumbered 19th page of application) (highlight added).

[4] Inova Fairfax Hospital's CT patient origin data confirm that ZIP Code 20190 (where Inova ER Reston is located) is the lowest volume ZIP Code within Inova' Fairfax's primary service area, constituting only 0.5% of CT scan volume and the source of only 617 CT scans in 2022 and 646 in 2023. See Attachment P to the Inova ER Reston COPN Request No. VA-8784. Of course, these figures include all CT scans performed at Inova Fairfax Hospital, not just those smaller number of CT scans that would be appropriate for the patient population served by Inova ER Reston.

[5] The SMFP's institutional need standard 12 VAC 5-230-80 makes clear that institutional need cannot be used to establish a new service. Therefore, the new CT service at Inova ER Reston cannot be approved under -80.

partnership with, Inova Health Care Services. The COPN program should not permit PD 8's dominant CT provider to expand its market share at the expense of other PD 8 providers with significantly fewer CT assets because the continued vitality of those other providers – like Reston Hospital Center – is necessary to serve as a meaningful alternative to Inova and promote beneficial institutional competition in PD 8. If Inova Fairfax Hospital genuinely needs to expand its CT service, there are a plethora of other, more-suitable sites for such expansion than a freestanding emergency room roughly a half mile away from Reston Hospital Center.

Clearly, introduction of CT imaging at Inova ER Reston would be contrary to public need. Because Inova ER Reston transfers out so many fewer CT patients than it projects serving, Inova ER Reston can only reach its projected utilization by significantly reducing the utilization of Reston Hospital Center's CT service in contravention of 12 VAC 5-230-110.

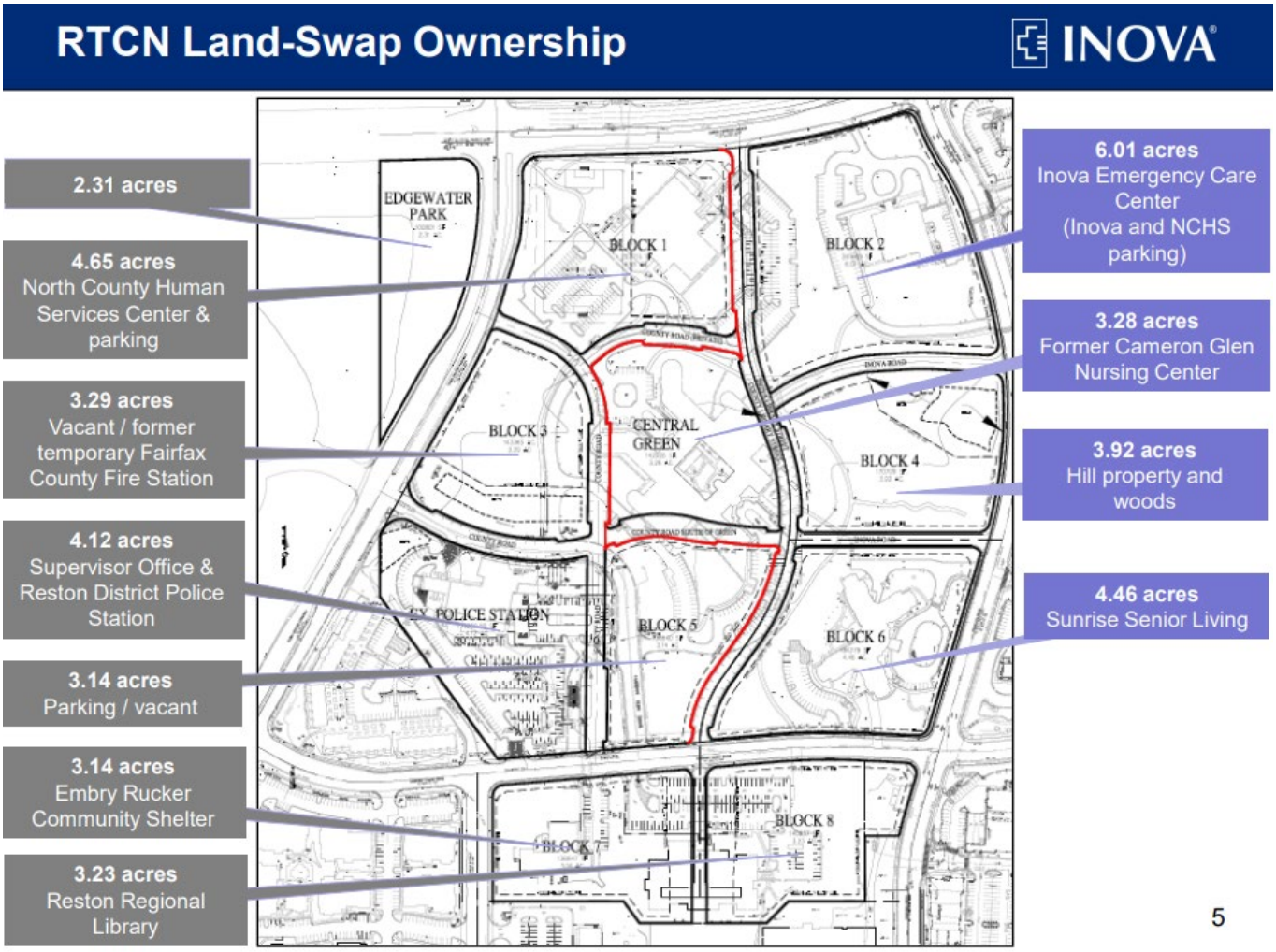
Moreover, Inova has previously acknowledged that CT imaging is not needed at Inova ER Reston. In 2013, when Inova sought COPN authorization to relocate the CT service from Inova ER Reston to Inova Emergency Room – HealthPlex Lorton, Inova acknowledged that a CT service at Inova ER Reston was not needed because patients had ready access at nearby Reston Hospital Center:

> Patients who might use Reston ECC would have convenient access to CT scanning at Reston Hospital Center and several other nearby services.[6]

Additionally, Inova's public statements about the planned development of Reston Town Center North ("RTCN") call into question Inova's long-term commitment to the continued operation of Inova ER Reston. Specifically, as shown on the following pages, Inova's June 13, 2023, presentation to the RTCN Community Task Force indicates that the Inova ER Reston site will be converted to residential use.

[6] January 7, 2013, Summary Minutes of HSANV Project Review Committee Meeting on COPN Request No. VA-7974 at 4. See Enclosure.

As shown below, slide 5 of that presentation shows the current location of the Inova ER Reston in so-called Block 2 in the upper right parcel of the RTCN property:[7]



[7] The presentation in which the slides reproduced in this letter appear can be found at https://www.fairfaxcounty.gov/publicworks/sites/publicworks/files/Assets/Documents/projects/Reston-Town-Center-North%E2%80%93June-13-2023.pdf

However, slide 4 of that same presentation shows that that Block 2 is planned to be converted to residential use, specifically "Multifamily units" and/or "Townhouses":

RTCN Block Concept Plan

INOVA

- Creates a coordinated development plan with the County, anchored by the Central Green.
- Possible ranges for future development options shown on Inova blocks.
- Opportunity for new residential while preserving the opportunity for healthcare uses.
- Task Force recommendations reflecting County and community objectives for County blocks will inform future rezoning.

4

Thank you for considering these comments. Reston Hospital Center respectfully asks that you deny COPN Request No. VA-8784. Please send me a copy of the DCOPN staff report on this project when that report is released.

With kindest regards, I remain

Very truly yours,

Thomas J. Stallings

Thomas J. Stallings

cc: Erik O. Bodin, III, Director, Division of Certificate of Public Need
Sharon K. Honaker, Project Review Analyst, Division of Certificate of Public Need
Dean Montgomery, Executive Director, HSANV
Elizabeth Breen

Enclosure: January 7, 2013, Summary Minutes of HSANV Project Review Committee Meeting on COPN Request No. VA-7974

196936161_2

Summary Minutes
Project Review Committee Meeting
Health Systems Agency of Northern Virginia
NVRC Conference Room
Fairfax, VA

January 7, 2013

Members Present

David Braun, Chairperson
Barbara Cohoon, RN
Judith Hines
Judith Randal Hines
Sally Patterson
Courtney Tierney

Staff Present

Ann McFeeley

Guests (Partial Listing)

Robin Adams, Director, Market Development, Sentara NVMC
Jolynn Aponte, Administrative Director, Inova Lorton HealthPlex
Deborah Blair, MD, Chair of the Department of Radiology, Inova Mount Vernon Hospital
Donald Brideau, MD, VP Medical Affairs, Inova Mount Vernon Hospital
Doug Cappiello, MD, Kaiser Permanente
Barbara Doyle, CEO, Inova Mount Vernon Hospital
Paul Dryer, Inova Health System
James Ecklund, MD, Chair, Department of Neurosciences, Inova Fairfax Hospital
Melissa Gibson, MD, Kaiser Permanente
Andrew Gill, Inova Health System
Paula Hancock, Kaiser Permanente
Marshall Mints, MD, Chair, Department of Radiology, Inova Fairfax Hospital
John Maguire, MD, Medical Director, Inova Reston, ECC
Peter Mellette, Counsel, InSight Health/CDI
Sharat Narayanan, MD, Kaiser Permanente
Robert Olshaker, MD, SNVMC
Nicole Paulk, Vice President Strategic Planning/Innovation, Inova Health System
Edward Rabbit, MD, Sentara Northern Virginia Medical Center
Michael Shuster, MD, Chair, Department of Emergency Medicine, Inova Mount Vernon Hospital
Kent Stevens, Berkeley Medical Group, Kaiser Permanente
Robert Theis, Executive Director, Inova Neuroscience Institute
Nathan VanGenderen, CFO,Sentara Northern Virginia Medical Center
Heidi Veltman, Kaiser Permanente
Marty Ward, Sentara Northern Virginia Medical Center
David Weintritt, MD, Sentara Northern Virginia Medical Center
Bruce Wollman, MD, Kaiser Permanente
Dave Winokur, Sentara Northern Virginia Medical Center

I. Call to Order, Introductions

David Braun, Chairperson, called the meeting to order at 7:30 PM. He announced that the HSANV Project Review Committee would hold public hearings on five COPN applications:

- Inova Fairfax Hospital, Expand CT Scanning Service (COPN VA-7975),
- Inova Health Care Services, Establish CT Scanning Service (COPN VA-7974),
- Sentara Northern Virginia Medical Center, Establish CT Scanning Service
- (COPN VA-7971),
- Kaiser Permanente Health Plan, Establish MRI Service (COPN VA-7927), and
- Sentara Northern Virginia Medical Center, Expand MRI Service (COPN VA-7972).

Braun welcomed those present, reviewed the agenda and hearing procedures, and initiated the introduction of Committee members. He said that without objection the applications would be taken up in the order presented on the agenda.

II. Conflicts of Interest

David Braun followed established HSANV conflict of interest procedures to determine whether any member of the Committee had a conflict of interest on any of the applications under review. No conflicts were declared, alleged, or otherwise identified.

III. Inova Hospital Fairfax Hospital, Expand CT Scanning Service (COPN VA-7975)

A. Staff Summary of the Applications

Ann McFeeley summarized the substance and nature of the three applications calling for expansion or relocation of CT scanning services. She noted that though the three proposals are considered competing applications, the substance of the proposals indicate clearly that the Inova Fairfax Hospital application, which calls for the introduction of intra-operative CT capability at the hospital, would not compete with either of the other proposals (were the projects implemented) or with any other diagnostic CT imaging service. McFeeley said the Inova and Sentara proposals to relocate CT scanners to Lorton are competing applications.

B. Applicant Presentation

Nicole Paulk, Vice President Strategic Planning, Inova Health System, introduced Inova Health System representatives (Marshall Mintz, MD, Chair Department of Radiology, Inova Fairfax Hospital, Robert Theis, Executive Director, Inova Neuroscience Institute and James Ecklund, MD, Chair, Department of Neurosciences, Inova Fairfax Hospital).

Paulk summarized the application, noting that the proposal is for a mobile CT scanner for intra-operative use at Inova Fairfax Hospital, that the project would be used for select surgery procedures as described in the application, and that the project is reasonably priced and would not compete with diagnostic CT scanning services. She said Inova believes the proposal to be consistent with applicable planning considerations.

Mintz, Theis and Ecklund described the scanner to be acquired and its capability, the neuroscience program at Inova Fairfax Hospital (IFH), the potential clinical value of the technology in spine and neurosurgery cases, the surgery case load at the hospital, and how the scanner would be used day-to-day in the IFH.

C. Committee Questions and Discussion

The Committee posed a number of questions about intra-operative CT scanning technology and how it would be used at Inova Fairfax. In response to those questions Ecklund, Mintz, Theism and Paulk stated,

- Because the equipment is mobile it could be used in a number of operating rooms, but its size and configuration means that it will be used on a select number of complex spine and neurosurgery cases and will be used primarily in the larger operating rooms where these cases are handled,
- The equipment is designed for intra-operative use and can be used without moving the surgical patient within or outside of the operating room,
- Technicians and other staff are available at the hospital,
- Introduction of the capability is a collaborative project will full support of the hospital's radiology and surgery departments and medical leadership,
- The CT scanner to be acquired is a self shielded, 32 slice unit
- The scanner operates at comparatively low radiation doses, and
- The project would not require space expansion or renovation.

D. Public Testimony

There was no public testimony.

E. Staff Recommendation

In response to committee questions, McFeeley indicated that the CT scanner that would be acquired could be used only at Inova Fairfax Hospital. Equipment and services authorized under the COPN program are site specific.

McFeeley stated that staff found no reason to question the value of the project or to oppose the application. She said staff believes Inova Fairfax Hospital is the appropriate location to introduced intra-operative CT scanning capability in Northern Virginia.

F. Committee Deliberation, Vote

Sally Patterson offered a motion to recommend approval of the Inova Fairfax Hospital application. Courtney Tierney seconded the motion. The motion passed six in favor (Braun, Cohoon, J. Hines, J. R. Hines, Patterson, Tierney) and none opposed.

IV. Inova Health Care Services, Establish CT Scanning Service (COPN VA-7974)

A. Applicant Presentation

Nicole Paulk, Vice President, Strategic Planning and Innovation, Inova Health System, introduced Inova representatives (Barbara Doyle, CEO, Inova Mount Vernon Hospital, Jolynn Aponte, Administrative Director, Inova Lorton HealthPlex, Deborah Blair, MD, Chair, Department of Radiology, Inova Mount Vernon Hospital, Donald Brideau, MD, VP Medical Affairs, Inova Mount Vernon Hospital, Michael Shuster, MD, Chair, Department of Emergency Medicine, Inova Mount Vernon Hospital, John Maguire, MD, Medical Director, Inova Reston, ECC) available to discuss the application.

Paulk summarized the proposal. She reviewed the recent history of Inova efforts to establish a CT scanner at the Lorton HealthPlex, noting that the 2011 proposal to establish a new service there was denied by the Commissioner of Health, with the suggestion that Inova consider relocating one of its CT scanners with low use to the site. Paulk said the scanner would be collocated with a full time emergency service, outpatient surgery, and a number of other outpatient diagnostic and treatment services. She said Inova believes the proposal satisfies all planning and regulatory considerations, including the applicable provisions of the Virginia State Medical Facilities Plan (SMFP).

Barbara Doyle, Donald Birdeau, Michael Shuster, Deborah Blair, and John Maguire discussed the relationship of Lorton HealthPlex to Inova Mount Vernon Hospital and to other Inova services in southeastern Fairfax County, the proposed changes at Reston Emergency Care Center, the implications of closing the Reston ECC scanning service, the clinical importance of CT scanning in diagnosing and treating medical problems, and the likely effects of establishing a CT scanning service in Lorton on other CT scanning services in southeastern Fairfax County.

B. Committee Questions and Discussion

In response to questions from the Committee, Paulk, Doyle, Birdeau and Maguire stated that,

- Low use of the Reston ECC scanner largely results from the proximity of CT scanning services at Reston Hospital Center and a number of other CT scanning programs,
- Patients who might use Reston ECC would have convenient access to CT scanning at Reston Hospital Center and several other nearby services,
- The Reston ECC CT scanner would be taken out of service, not moved to Lorton, and
- Reston ECC would not offer CT scanning after the Lorton HealthPlex CT scanner is placed in service.

C. Public Testimony

There was no public testimony.

D. Staff Recommendation

Ann McFeeley summarized the staff evaluation of the application. Based on the data and information presented in the staff report on the application, she said staff recommends approval of the project.

E. Committee Deliberation, Vote

Committee discussion and vote on the proposal were deferred until the competing Sentara Northern Virginia Medical Center application could be heard.

V. Sentara Northern Virginia Medical Center, Establish Lorton, VA, CT Scanning Service (COPN VA-7971)

A. Applicant Presentation

Nathan VanGenderen, Chief Financial Officer, Sentara Northern Virginia Medical Center (SNVNMC), introduced hospital representatives (Robin Adams, Robert Olshaker, MD, David Weintritt, MD, Edward Rabbit, MD) available to respond to questions about the application.

VanGenderen began the presentation with a statement offered ostensibly to place the SNVMC proposal in context. He stated:

> "The first thing I'd like to address—I don't know if you have had time to review the staff report—but I just want to go ahead right up front and get something out there on the table. The---I was going to talk a little bit about the history and don't want to go through each of these slides in detail but I kinda want to set the appropriate context for the historical relationship between the community of Lorton and Potomac Hospital, which is the previous version of Sentara Northern Virginia Medical Center. In 1999 –I won't do it year by year I promise, but in 1999 Potomac Hospital formally affiliated with Inova Health System. I don't know if that's common knowledge, public knowledge, I am relatively new to the area.
>
> That formation in a formal relationship—uh I can't really talk about specifics in terms of disclosure into the public record, but that affiliation really provided support that was very much needed for Potomac Hospital but also restricted the service area—uh--based on what–uh-- I mean I guess the plain way to say it on what Inova would have deemed as appropriate service areas for appropriate hospitals. I think it is safe for me to say that in Inova's opinion that Lorton would have been more appropriately served by the Inova Mount Vernon Hospital versus Potomac Hospital in Woodbridge serving that community.
>
> So, I want you to kinda keep that in the back of your mind as we go through a few points here, simply because I know that in the staff report it will mention that maybe this project has merit, everything about it looks good, we would let you do it except it does not make sense. All of these things would point to you putting resources into a community that you serve and it does not appear that you are serving the Lorton community. I guess my response to that would be there have been these artificial barriers to that in the past that we are at this point trying reverse or turn slightly differently.
>
> I'll actually stop there. Are there any questions about that because I think that is a key point.[1]
>
> OK."

VanGenderen reviewed the application using a set of slides to emphasize what the hospital believes to be key aspects of the proposal. The presentation, which ranged from background information on Sentara Healthcare to the applicant's rationale for moving one of the hospital's CT scanners to Lorton, is enclosed (Attachment 1).

Points and arguments presented include:

- After acquiring Potomac Hospital in 2009, Sentara Healthcare has moved quickly and purposefully to stabilize the hospital's economic standing, update and modernize the facility, and develop an associated ambulatory care network similar to that Sentara employs elsewhere in Virginia,

[1] There were no questions from the Committee.

- Sentara purchased the CT scanner that had been jointly owned by Potomac Inova Health Alliance (PIHA) in 2011,
- The scanner (a 64-slice unit located at Prince William Parkway) has low use and is redundant in that it serves the same population served by SNVMC's other scanning services,
- The project entails moving an underused utilized CT scanner to the Lorton community which has no CT scanner and limited access to CT scanning,
- The service would be located with other diagnostic imaging services,
- SNVMC will provide substantial charity care,
- This project offers a potential choice of services for the Lorton community and is consistent with the COPN law's mandate to consider a project's fostering of institutional competition
- The project would be modeled after Sentara's successful outpatient diagnostic and treatment centers, including the recently opened SNVMC Lake Ridge center,
- The PIHA CT service has low use and is not likely to succeed in its current configuration because of contractual arrangements/limitations (which cannot be revealed because SNVMC "cannot disclose too much in the public record about PIHA"), and
- CT scanning services at the hospital and at the hospital's Lake Ridge service can readily serve those who would otherwise use the scanner to be moved.

Robert Olshaker, MD, David Weintritt, MD, and Edward Rabbit, MD, discussed their clinical experience and medical practices in the Lorton area, at Sentara Northern Virginia Medical Center, and at SNVMC's Lake Ridge ambulatory care center. All three indicated that CT scanning has become an essential diagnostic tool for most medical practices. They stated that it would be helpful to physicians and patients alike to have CT scanning in Lorton, that they would use the Lorton service if it is developed, and will continue to use other SNVMC scanning services, as well as other service providers in the region, when it is convenient and clinically appropriate.

C. Committee Questions and Discussion

In response to questions from the Committee, VanGenderen, Robin Adams, and other SNVMC representatives stated that:

- The current site of the CT scanner that would be relocated is not appropriate and is inferior to the proposed Lorton location,
- The ready availability of SNVMC CT services in Woodbridge and Lake Ridge make the former PIHA scanner redundant, unnecessary,
- Lorton is nearer Sentara Northern Virginia Medical Center (SNVMC) than to Inova Mount Vernon Hospital (IMVH) and, therefore, more properly in the SNVMC service area than the IMVH service area,
- SNVMC will have a charity care percentage higher than the regional average, and
- There is sufficient need/demand in the Lorton area to justify both the Inova and Sentara proposals.

D. Public Testimony

There was no public testimony.

E. Staff Recommendation

Based on the data and discussion of the application in the staff report on the competing proposals to open CT scanning services in Lorton, McFeeley said staff recommends that the application not be approved.

F. Committee Deliberations, Votes

Inova Lorton HealthPlex

Sally Patterson offered a motion to recommend approval of the Inova Lorton HealthPlex application. Judy Randal Hines seconded the motion. The motion passed six in favor (Braun, Cohoon, J. Hines, J. R. Hines, Patterson, Tierney) and none opposed

Sentara Northern Virginia Medical Center – Lorton

Courtney Tierney offered a motion to recommend approval of the Sentara Northern Virginia Medical Center application. Barbara Cohoon seconded the motion. The motion passed three in favor (Cohoon, J. Hines, Tierney) and one opposed (Braun), with two abstentions (J. R. Hines, Patterson).

VI. Kaiser Permanente Health Plan, Establish MRI Service (COPN VA-7927)

A. Applicant Presentation: Inova ASC Lorton

Doug Cappiello, MD, Kaiser Permanente Physician in Chief for Northern Virginia, introduced himself and other Kaiser representatives (Heidi Veltman, Northern Virginia Area Administrator, Bruce Wollman, MD, Regional Medical Director for Imaging, and Melissa Gibson, MD, and Sharat Narayanan, MD, Kaiser physicians) available to discuss the application. Cappiello distributed a set of PowerPoint slides that outline key aspects of Kaiser Permanente Health Plan and the proposal to establish an MRI service in Woodbridge, VA.

Gibson and Narayanan, Kaiser physicians, described their day-to-day medical practices within Kaiser health plan, the value of and need for reasonably convenient diagnostic imaging services, including MRI scanning, and the policies and practices in place at Kaiser to ensure quality and efficient service delivery.

B. Committee Questions and Discussion

In response to questions from the Committee, Cappiello and other Kaiser representatives stated that:

- About 30% of Kaiser's Northern Virginia subscribers live in the Route 1/I 95 corridor and would be likely to use the Woodbridge scanner,
- Average MRI service volumes of the two Kaiser MRI scanners now in service exceed the nominal Virginia SMFP volume threshold,
- A third scanner, located in Woodbridge, would permit Kaiser serve the large majority of its Northern Virginia MRI patients locally in Kaiser services, avoiding referring patients to Kaiser services outside the region or purchasing nonemergency scans at other service providers,
- The project would not affect other MRI service providers materially, and
- The project would reduce overall MRI costs within in the health plan.

C. Public Testimony

There was no public testimony.

D. Staff Recommendation

Based on the data and discussion of the application in the staff report, McFeeley said staff recommends that the application be approved.

E. Committee Deliberation, Vote

Sally Patterson offered a motion to recommend approval of the Kaiser Permanente Health Plan application. Judy R. Hines seconded the motion. The motion passed six in favor (Braun, Cohoon, J. Hines, J. R. Hines, Patterson, Tierney) and none opposed.

VII. Sentara Northern Virginia Medical Center, Expand MRI Service (COPN VA-7972)

A. Applicant Presentation

Marty Ward, SNVMC Senior Director for Ambulatory Services, introduced Sentara NVMC representatives present (Robin Adams, Robert Olshaker, MD) to discuss the application. Ward distributed a set of slides outlining key aspects of the application (Attachment 3).

Ward and Olshaker stated that, though technically below the SMFP service volume threshold, MRI service volume at SNVMC is growing and is expected to exceed 5,000 procedures within the next couple of months. They argued that approval of additional capacity now is appropriate to permit timely expansion of the service and to permit more effective patient scheduling and more efficient operations at the hospital.

Applicant spokesmen noted that SNVMC is one of the few hospitals in the region with only one MRI scanner and that a second scanner would improve service delivery considerably, both at the hospital proper and in the Lake Ridge outpatient setting. They cited the recent opening of SNVMC's ambulatory care center in Lake Ridge, and the favorable response to that service by physicians and patients alike, as an indication that the center is the appropriate location for the second hospital scanner.

B. Committee Questions and Discussion

In response to questions from the Committee, Ward and Olshaker stated that

- Patient scheduling is much easier in an outpatient setting, and adding a second scanner at Lake Ridge would reduce the number of outpatients using the hospital based scanner, permitting more flexibility in accommodating in hospital patients who need MRI scans,
- If authorized, the scanner purchased will be a large bore state-of-the-art unit,
- The scanner would be housed in fixed site trailer adjoining the ambulatory care center in Lake Ridge.

C. Public Testimony

Peter Mellette, counsel to InSight Health, spoke to remind the Committee that InSight has a proposal to add a new MRI scanner to its Prince William County service pending before the Virginia Commissioner of Health. He noted that the InSight service serves essentially the same population that a SNVMC scanner in Lake Ridge would serve and that the InSight service has substantially higher service volume than the SNVMC service.

Mellette said the InSight Health does not oppose the SNVMC project but suggests that is at least premature, given that the SNVMC 2012 service volume was less than 5,000 scans and the InSight proposal will not be decided until May of 2013. Mellette also argued that the InSight proposal compares favorably in a number of respects, especially in economic terms, to the SNVMC proposal.

Attachment 4 contains Mellette's testimony.

D. Staff Recommendation

Ann McFeeley outlined the options available to the committee in handling the application, but did not offer a specific recommendation.

E. Committee Deliberations, Votes

Courtney Tierney offered a motion to recommend approval of the Sentara Northern Virginia Medical Center application. Sally Patterson seconded the motion. The motion passed six in favor (Braun, Cohoon, J. Hines, J. R. Hines, Patterson, Tierney) and none opposed.

VIII. Adjourn

Braun adjourned the meeting at 10:25 PM.

Respectfully submitted,

Dean Montgomery

Attachments (4)

Attachment 4

Exhibit A – Inova Care

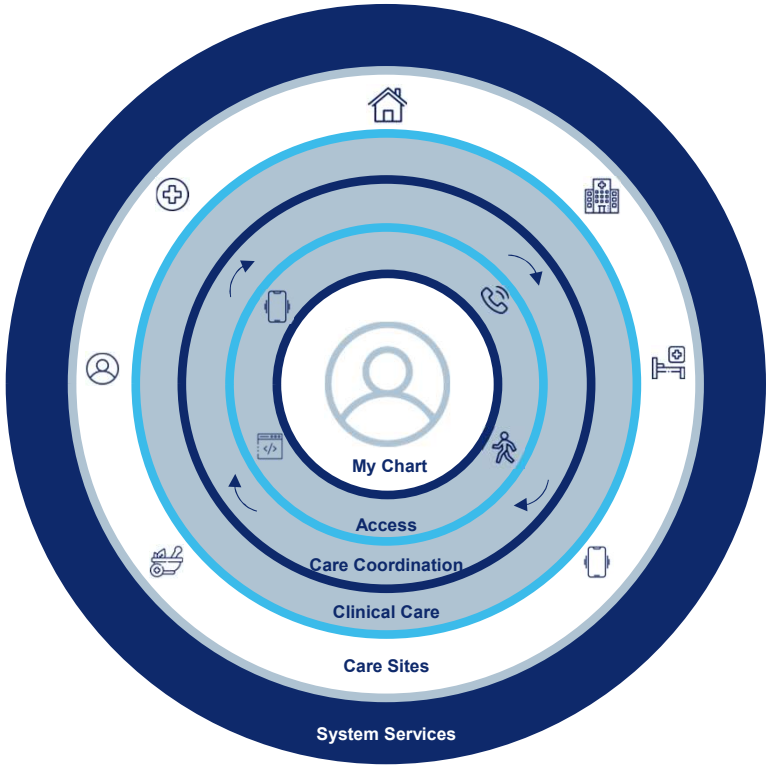
Our commitment to our patients and our community:

Mandate

Provide a people-centered, high reliability, high value, seamless system of care.

Our Imperatives for Transforming Care

- We must create an environment of zero harm.
- We must know each patient and honor what matters most to them with empathy and compassion.
- We must create a culture of psychological safety that empowers each team member to fully engage.
- We must collaborate in teams with equal voices, embracing patients and their families as integral members of the care team.
- We must embrace and practice best evidence, forgoing tradition and individual preference.



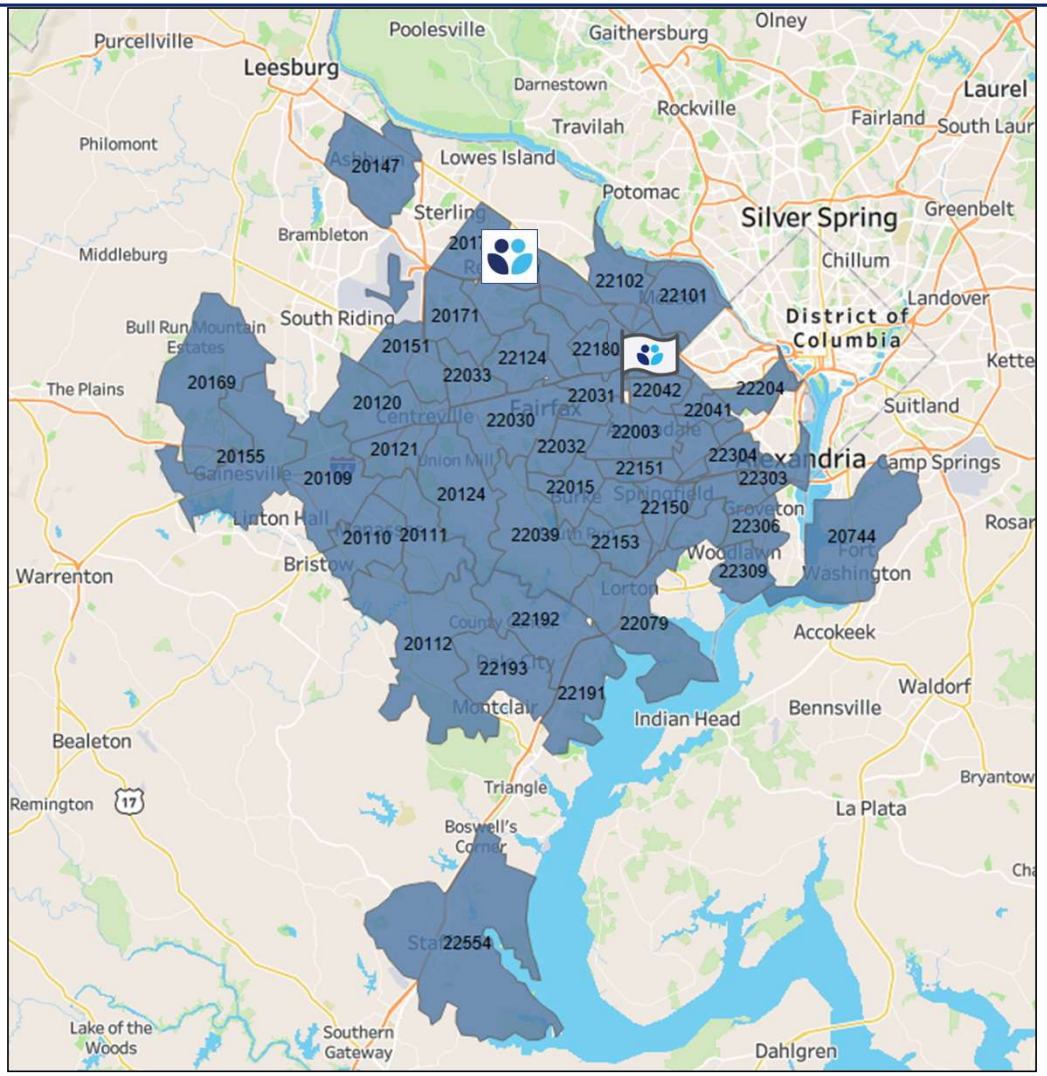
Individualized Caring Relationships

Exhibit B – Map of Inova Fairfax Hospital CT Primary Service Area

- **The Emergency Room – Reston/Herndon is within Inova Fairfax Hospital's CT Primary Service Area (top 75% Zip Codes by patient origin)**

Inova Fairfax Hospital

Inova Emergency Room – Reston/Herndon



Zip	County	City	SA
20109	Prince William County	Manassas	PSA
20110	Manassas City County	Manassas	PSA
20111	Prince William County	Manassas	PSA
20112	Prince William County	Manassas	PSA
20120	Fairfax County	Centreville	PSA
20121	Fairfax County	Centreville	PSA
20124	Fairfax County	Clifton	PSA
20147	Loudoun County	Ashburn	PSA
20151	Fairfax County	Chantilly	PSA
20155	Prince William County	Gainesville	PSA
20169	Prince William County	Haymarket	PSA
20170	Fairfax County	Herndon	PSA
20171	Fairfax County	Herndon	PSA
20190	Fairfax County	Reston	PSA
20191	Fairfax County	Reston	PSA
20744	Prince George's County	Fort Washingto	PSA
22003	Fairfax County	Annandale	PSA
22015	Fairfax County	Burke	PSA
22030	Fairfax City County	Fairfax	PSA
22031	Fairfax County	Fairfax	PSA
22032	Fairfax County	Fairfax	PSA
22033	Fairfax County	Fairfax	PSA
22039	Fairfax County	Fairfax Station	PSA
22041	Fairfax County	Falls Church	PSA
22042	Fairfax County	Falls Church	PSA
22043	Fairfax County	Falls Church	PSA
22044	Fairfax County	Falls Church	PSA
22046	Falls Church City County	Falls Church	PSA
22079	Fairfax County	Lorton	PSA
22101	Fairfax County	McLean	PSA
22102	Fairfax County	McLean	PSA
22124	Fairfax County	Oakton	PSA
22150	Fairfax County	Springfield	PSA
22151	Fairfax County	Springfield	PSA
22152	Fairfax County	Springfield	PSA
22153	Fairfax County	Springfield	PSA
22180	Fairfax County	Vienna	PSA
22181	Fairfax County	Vienna	PSA
22182	Fairfax County	Vienna	PSA
22191	Prince William County	Woodbridge	PSA
22192	Prince William County	Woodbridge	PSA
22193	Prince William County	Woodbridge	PSA
22204	Arlington County	Arlington	PSA
22303	Fairfax County	Alexandria	PSA
22304	Alexandria City County	Alexandria	PSA
22306	Fairfax County	Alexandria	PSA
22309	Fairfax County	Alexandria	PSA
22310	Fairfax County	Alexandria	PSA
22311	Alexandria City County	Alexandria	PSA
22312	Fairfax County	Alexandria	PSA
22314	Alexandria City County	Alexandria	PSA
22315	Fairfax County	Alexandria	PSA
22554	Stafford County	Stafford	PSA

Exhibit C – Inova Emergency Room – Reston/Herndon CT Volume Projection Methodology

Population Projections

	Est. 2023	2024	2025	2026	2027	2028	2029	2030
Population Projections - IFH SA (PD 8)	2,592,739	2,623,852	2,655,338	2,687,202	2,722,136	2,757,524	2,793,371	2,829,685
Population Growth		1.2%	1.2%	1.2%	1.3%	1.3%	1.3%	1.3%

Source: Weldon Cooper

Inova Emergency Room - Fairfax City 2023 CT Utilization

	2023 ED Visits
ECC Fairfax	15,180
CT Scans	5,521
CT Visits	4,064
Scans per ED Visit	0.36

Inova Emergency Room - Reston/Herndon CT Projection Methodology

				Projected Year 1+2	
Visit Volumes	2023	2024	2025	2026	2027
ED Visits	8,974	9,082	9,191	9,301	9,422
ED CT Scans				3,383	3,427
Elective CT Scans				670	1,005
Total CT Scans				4,053	4,432

ED Visits projected based on population growth

ED CT Scans projected based on Fairfax City CT utilization

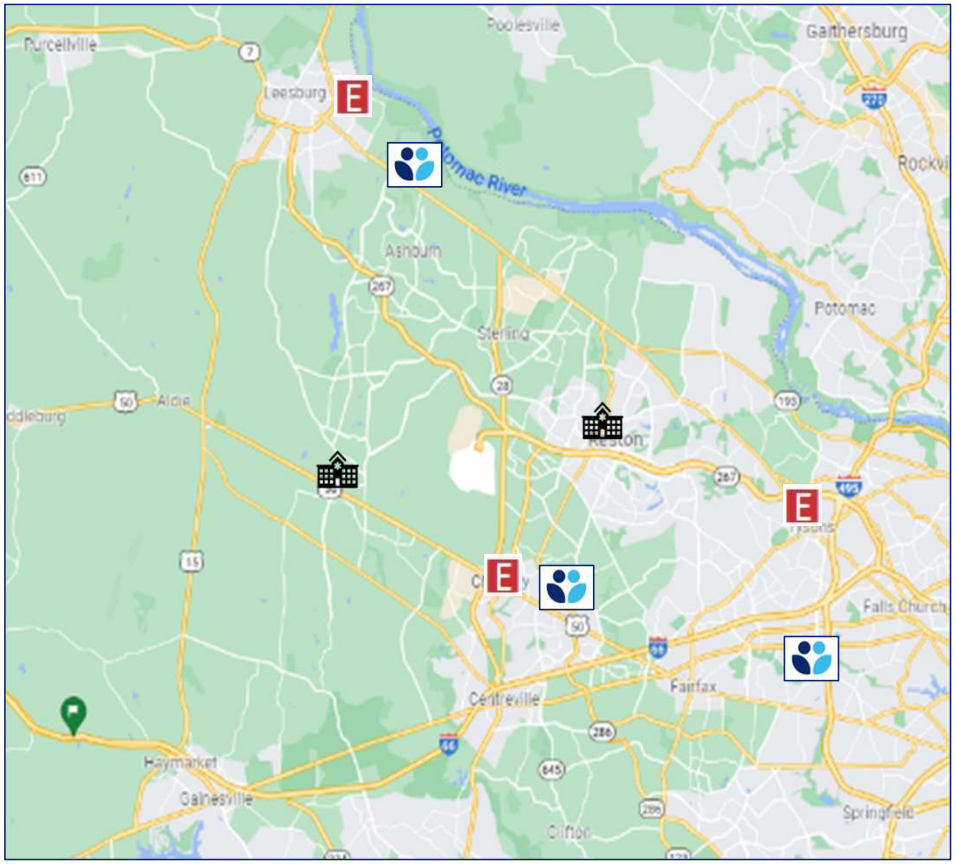
Elective CT Scans based on other Inova emergency sites

- **This is an existing emergency department that in 2024 will serve over 9,000 patients.**
- **Projections integrate population growth and CT use rates from our Inova Fairfax City Emergency Room**
- **CT volumes are based on serving only Inova's existing patients**

Exhibit D – Map of Operational and Approved HCA Freestanding Emergency Centers

Legend:

- HCA Hospital
- HCA Freestanding ER
- Inova Hospital



- **HCA has three operational and approved freestanding emergency rooms in Planning District 8**
- **All are close to Inova hospitals, and all were approved by the state health commissioner**

- **Inova is dedicated to serving the Reston/Herndon community**
- **With the land swap Inova would own blocks 2, 4, and 6**
- **The current Inova Emergency Room building is sited in Block 2**
- **If we redevelop there is 150,000 square feet of non-residential space in blocks 4+6 which could be the future site of a new emergency room**

RTCN Block Concept Plan

- Creates a coordinated development plan with the County, anchored by the Central Green.
- Possible ranges for future development options shown on Inova blocks.
- Opportunity for new residential while preserving the opportunity for healthcare uses.
- Task Force recommendations reflecting County and community objectives for County blocks will inform future rezoning.