Health Systems Agency of Northern Virginia Board of Directors Meeting March 10, 2025

Members Present

Patricia Deitos, RN
Michelle Kimmel
Pamela Kincheloe, RN, Chairperson
Lydia Lawrence
Patrice Lepczyk
Douglas Samuelson
Robert Sharpe

Staff Present

Ann McFeeley Dean Montgomery

Guests (Partial List)

Lance Boyd, CEO, Fairfax Radiology Centers
Carol Burchett, Chief Strategy Officer, Fairfax Radiology Centers
Audrey Fisher, CEO, The Cardiovascular Group (Virginia Heart)
Peter Mellette, Goodman, Allen, Donnelly, Counsel Virginia Heart
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
Adrian Stanton, Vice-President, Virginia Hospital Center
Ketan Trivedi MD, Chief Medical Officer, Virginia Heart
Spencer Wildonger, Director of Planning, Transformation, JHU Medicine

. Call to Order

Pam Kincheloe, RN, Chairperson, Health Systems Agency of Northern Virginia (HSANV), called the meeting to order at 7:36 PM. She welcomed guests and reviewed the agenda.

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

- The Cardiovascular Group (d/b/a Virginia Heart), establish a cardiac PET-CT service (COPN Request VA-8794)
- IFRC, establish a CT scanning service (COPN Request VA-8795)

II. Previous Minutes

The board approved minutes of the December 16, 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 COPN applications on the agenda. No conflicts were declared, alleged, or otherwise identified.

IV. COPN Applications

1. Virginia Heart, Establish Cardiac PET-CT Service, (COPN Request VA 8794)

Virginia Heart Presentation

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

- Virginia Heart is the largest cardiology practice in the region. It has scores of physicians and support staff, twelve practice locations, and a patient base that generates more than 170,000 patient visits annually. The group has grown rapidly in recent years.
- PET-CT scanning is the preferred diagnostic imaging option for many patients with coronary artery disease. It both complements, and in some cases, substitutes for other myocardial perfusion imaging studies.
- Recently, Virginia Heart has obtained two certificates of public need (COPNs) to establish cardiac PET imaging services: one for its Falls Church office (Telstar Court), the other for its Lansdowne (Loudoun County) office.
- The Telstar Court service is open and operates at capacity. It can serve only a fraction of the practice's internal demand (referrals from within the medical group).
- The second cardiac PET service, authorized earlier this year, is being developed.
- With two services/scanners, Virginia Heart expects to be able to respond to about half of potential demand from the group's cardiologists. Consequently, it proposes adding a third cardiac PET scanning system to be located at its City of Alexandria office (Mark Center).
- The capital cost of the project, about \$3.8 million, is comparable with that of the preceding projects.
- Virginia Heart projects (*pro forma* budget assumes) a charity care commitment of about 5% of projected net revenue.
- There is no indication or expectation that the project would affect demand among other local PET-CT services negatively.

A copy of the slides presented by Virginia Heart representatives in support of the application are attached (Attachment 1).

Board & Staff Ouestions, Discussion

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

- The second Virginia Heart cardiac PET service, authorized about a month ago, will be open later this year. It will be operating at capacity shortly after opening.
- Most of Virginia Heart's current cardiac PET patients are Medicare fee-for-service patients. The
 practice also has coverage agreements with United Health and Aetna. Insurance coverage of cardiac
 PET imaging is evolving. It is expected to expand steadily.
- Given the value of cardiac PET imaging, and its rapid adoption as the standard of care by the medical community, adding capacity elsewhere in the region is not likely to affect demand at Virginia Heart's services.

Public Comment

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

Applicant Final Summary

Mellette summarized the benefits of the proposal and thanked the board for its consideration of the proposal. He offered to answer any additional questions.

Staff Recommendation, COPN Request VA-8794

Dean Montgomery referred members to the conclusions reached in the agency staff report on the application. Based on the data and information presented in the report, on recent service volumes at the applicant's service, on the testimony presented by the applicant, and on the absence of opposition to the project, Montgomery recommended approval of the application.

Board Deliberation and Vote, COPN Request VA-8794

Patrice Lepczyk offered a motion to recommend approval of the application. Lydia Lawrence seconded the motion. The motion passed by a vote of six in favor (Deitos, Kimmel, Kincheloe, Lawrence, Lepczyk, Sharpe) and no one opposed.

2. IFRC, establish a CT scanning service (COPN Request VA-8795)

IFRC Presentation

Lance Boyd, CEO, Fairfax Radiology Centers, introduced himself and others representing the applicant: Carol Burchett, Chief Strategy Officer, Fairfax Radiology Centers, and Patrick Oliverio, MD, IFRC and Fairfax Radiology Consultants.

Boyd, Burchett and Oliverio presented the application. They focused on the desire to maintain efficient CT scanning services within IFRC, on the necessity of replacing and relocating the dated IFRC-Sterling CT scanner, and on the high use of IFRC CT scanners. Among other considerations, they emphasized:

- The proposal is a necessary maintenance of effort project. It entails the replacement of the CT scanner at IFRC's Sterling, Virginia service with a new scanner at its Ballston office. As such, it is inventory neutral.
- The CT scanner to be replaced has reached the end of its useful life and must be replaced, onsite or elsewhere.
- Onsite replacement of the Sterling scanner is not a practical option because the lease on space housing the scanner will terminate in about a year and the site vacated.
- The replacement and relocation of the dated Sterling scanner, which was placed in service in 2005, should result in 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).

Board & Staff Questions, Discussion

In response to questions Boyd, Burchett and Oliverio stated:

- Those now using the Sterling service will have access to a number of nearby CT scanning services when the imaging center closes.
- The project will not increase IFRC capacity. It is inventory neutral.
- The replacement scanner is expected to be used more heavily at the Ballston site than the scanner currently at the Sterling site.
- IFRC will close the Sterling imaging center when the office lease expires in early 2027.

Public Comment

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

Final Summary

Boyd thanked the board for its consideration of the proposal.

Staff Recommendations: COPN Request VA-8795

Montgomery noted that the IFRC proposal appears to be a necessary replacement and relocation project. The scanner to be replaced has reached the end of its useful life. Replacement on site is not a practical option given that the lease on the space accommodating the scanner will be vacated in about a year and a half. Based on these circumstances and high use of IFRC diagnostic imaging services, the project appears to be warranted and prudential.

The project is consistent with applicable provisions of the Virginia State Medical Facilities Plan. It is worth noting that onsite replacement of CT scanners is subject to notification/registration. The IFRC proposal is subject to COPN review because replacement of the scanner off site is deemed the establishment of a new service.

Based on these considerations, on the data and information presented in the agency staff report on the application, and on the testimony presented by the applicant, Montgomery recommended approval of the application.

Board Deliberation and Vote, COPN Request VA-8795

Douglas Samuelson offered a motion to recommend approval of the application. Patti Deitos seconded the motion. The motion passed by a vote of seven in favor (Deitos, Kimmel, Kincheloe, Lawrence, Lepczyk, Samuelson, Sharpe) and no one opposed.

V. Review of Recent COPN Decisions

Doug Samuelson called attention to the case decision memorandum on the recently approved Loudoun ProCo nursing home expansion project, contrary to the advice and recommendations of HSANV and the Commissioner's staff (DCOPN). The board and staff discussed the nature and history of the project and similar authorizations to transfer nursing home capacity (beds) from southwest Virginia to northern Virginia.

VI. Other Business

The next board meeting was set for Monday, April 14, 2025.

VII. Adjourn

Kincheloe adjourned the meeting at 9:15 PM.

Respectfully submitted,

Dean Montgomery

Attachments (1)

Attachment 1

Virginia Heart Cardiovascular PET-CT Project Alexandria

Audrey Fisher, MPH, Chief Executive Officer
Ibrahim Saeed, MD, Medical Director of Nuclear Imaging
Ketan Trivedi, MD, Chief Medical Officer
Peter Mellette, Esq.

March 10, 2025



Virginia Heart Profile

- Established in the early 1980's
- 94 providers, including 60 MDs, 34 APPs, 500+ Employees
- Offering:
 - -General Cardiology
 - -Interventional Cardiology
 - -Structural Heart
 - -Electrophysiology

- -Advanced Cardiovascular Imaging
- -Advanced Heart Failure
- -Congenital Heart Care
- -Sleep Medicine
- 10 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)

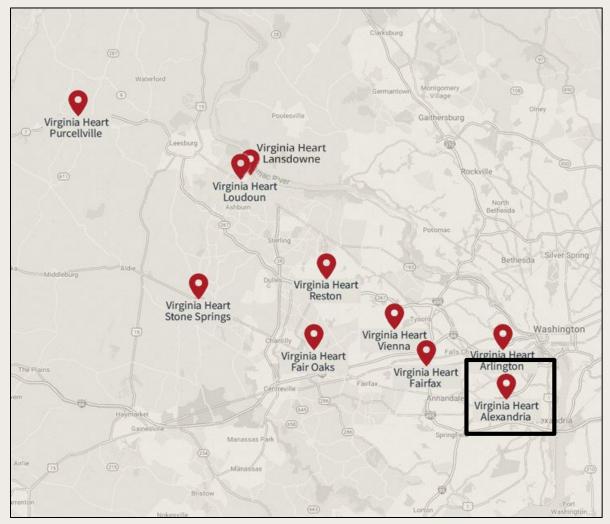
	2024*	2023	2022	2021	2020
Patient Encounters	171,184	162,134	157,029	151,633	139,981
Outpatient Visits	135,350	124,684	120,006	114,466	109,180
Inpatient Visits	35,834	37,450	37,023	37,167	29,801
Caths/ PCI	3,440	3,165	3,396	3,213	3,092
SPECT	5,258	6,211	5,986	5,999	5,195
PET	2,363	718	NA	NA	NA

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

*2024 Data Annualized from Jan-Oct 2024)



Virginia Heart Locations



Alexandria Location: Proposed Site



4825 Mark Center Drive – site of existing Virginia Heart Alexandria Clinic



Presence in PD8

- PD8 contains over 2.6 million people
 - Virginia Heart draws primarily from Arlington, Alexandria, Fairfax, and Loudoun
 - Project scope is <u>not</u> 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
 - Alexandria site will serve Eastern PD 8
 - Alexandria & Arlington areas represent ~25% of Virginia Heart patients



Project Rationale

- Cardiovascular PET-CT is the superior technology for non-invasive evaluation of ischemic heart disease
- Cardiac PET is rapidly replacing and/or augmenting SPECT as part of the standard in-office ancillary testing offered by 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
- Reduces retesting, unequivocal results, and unnecessary cardiac catheterization due to greater sensitivity and specificity
- Results in cost savings due to fewer unnecessary procedures
- Will serve 2000+ patients not currently able to be seen at Telestar PET/CT (or at Lansdowne PET/CT when available)

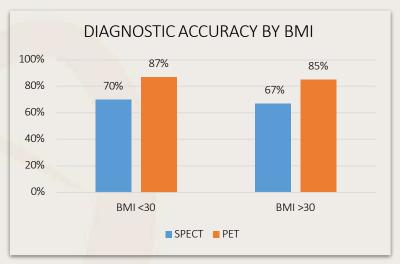


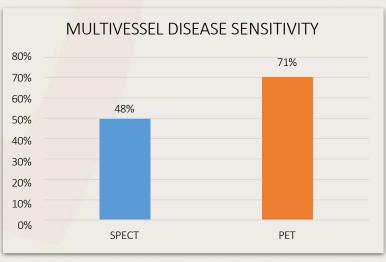
Important Properties of Cardiovascular

PET/CT v. SPECT

Higher diagnostic accuracy

- Consistently high-quality images
- Lower radiation exposure
- Shorter testing time
- Stronger 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







PET vs SPECT

Per literature, PET scanning as first-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

Why do we NEED this in Alexandria?

- Demand for Cardiology Services increasing significantly since the pandemic and with the growing & aging population
- Since 2020, Virginia Heart has increased providers by 32% to meet demand and has increased new patients by 55%; this equates to increasing demand for cardiac testing, including PET
- Not enough capacity at Telestar and Lansdowne to serve projected patient demand
- Recently established and/or contracts in-negotiation with private payors will open this up to an additional 65% of patients
- Currently Medicare FFS Only; minimum demand is projected to be
 >10K scans per year when it is opened to private payors



Why do we NEED this in Alexandria?

- Total demand is difficult to quantify because many patients who are not candidates for SPECT referral (morbidly obese, claustrophobia, mobility issues) are candidates for PET, so there is unmet demand
- Many patients in Eastern PD8 are unable or unwilling to travel to Falls Church; Alexandria patients, in particular, face socio-economic challenges – e.g. patients taking public transportation
- ~25% of Virginia Heart patients are in Eastern PD8 having PET in this location makes it convenient & accessible to a large portion of patients
- Location is critical for Cardiologist oversight & emergency response, as well as PET physical requirements (load-bearing, vibration, getting it into an existing building); a unique, viable location is currently available and not likely to be in the future



Charity Care & Community Benefit

- Proactive outreach for calcium scoring at health fairs and community events to underserved communities
- Virginia Heart providers routinely volunteer at multiple free or low-cost clinics
- Charity Care Policy with sliding scale fee for services
- Virginia Heart Community Foundation
- HSANV Staff Summary recognized Virginia Heart's history of service to medically indigent patients

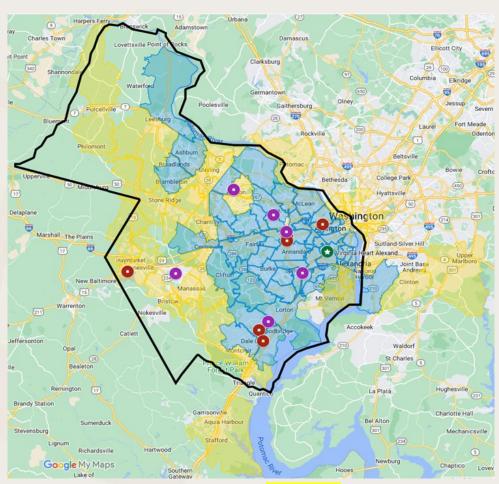


Collaboration with Inova

- 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.

Health Planning Considerations

- 1. The proposed project will provide improved 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
 - Improves distribution of PET/CT to serve
 Virginia Heart patients in Alexandria,
 Arlington, and Eastern Fairfax County
 - Existing and approved PET/CT units "will serve less than 2/3 of current demand within practice"
 - "No indication or reason to believe that the project will affect demand at competing services"
 - "Applicant has a history of equitable service to medically indigent patients"
 Source: HSANV staff summary 2/28/25



Virginia Heart Primary and Secondary Service Areas

- 2. The proposed project will 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 easternmost 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
 - "Inova and Virginia Heart are aligned in our mission, vision and values...We are supportive of Virginia Heart's COPN application to add an additional Cardiac PET/CT in Alexandria." Christopher O'Connor, MD, President, Inova Schar Heart & Vascular
 - "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 acquisition of a 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 current SPECT and PET/CT utilization of 8193 annual MPI procedures supports up to 3 cardiovascular PET/CTs at 2,000+ annual procedures each; over 100 PET/CT orders/month not met on Medicare FFS population; providers currently not referring other commercial patients
 - Virginia Heart's Alexandria location would serve a different primary service area than existing and approved cardiac PET/CT sites
 - SMFP PET criteria are outdated and not achievable based on throughput experience
 - 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
 - Use of PET/CT will improve patient outcomes and reduce overall costs of care
 - No impact on other PET/CT providers



4. The project is consistent with specific SMFP provisions

12VAC5-230-200 Travel Time:

- No cardiovascular PET/CT service currently available in Alexandria – improves service area access
- Mark Center's address would improve access to Alexandria, Arlington, E. Fairfax Virginia Heart patients



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

- 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 Alexandria
- 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 \$3,687,746 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 Alexandria
 - Virginia Heart's volume of over 8,000 MPIs/year on very limited segment of patients supports project
 - Use solely for cardiovascular studies within practice would introduce preferred technology without impacting existing PET/CT providers
 - b. The project is feasible as proposed
 - Development and operating costs are reasonable [per HSANV staff]
 - Renovation of space adjacent to existing clinic with limited construction costs
 - Minimal additional human resources/staffing necessary
 - Timing of building availability for PET/CT expansion is now
 - c. The project offers significant improvements and innovations in delivery of cardiology care
 - Well-established technology promotes delivery of both quality and cost-effectiveness in delivery of cardiology care on outpatient basis
 - Improvements: high-diagnostic accuracy, consistent high-quality images, low radiation exposure, short-acquisition protocols, ability to quantify myocardial blood flow, prognostic power
 - Innovations: Eliminates further downstream testing and reduces costs and risks associated with unnecessary cardiac catheterizations



Thank You!

