VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

March 21, 2023

RE: COPN Request No. VA-8654
Nova Cardiovascular Care, Inc.
Woodbridge, Virginia
Establish PET Services with One Fixed Site Cardiac PET Scanner

Applicant

Nova Cardiovascular Care, Inc. ("NCC") is a proprietary corporation who is neither wholly or partially owned or operated by another nor does NCC wholly or partially own any subsidiaries. NCC is located at 1990 Old Bridge Road, Suite 101, Woodbridge, Virginia 22192, within Planning District ("PD") 8, embedded in Health Planning Region ("HPR") II.

Background

Myocardial perfusion imaging (MPI) is an assessment tool for known or suspected coronary artery disease (CAD). Single photon emission computed tomography (SPECT) has historically been the modality for MPI assessment; however, Cardiac PET, using tracers such as rubidium-82, are available and yield a much more accurate and detailed image.[1] SPECT images give useful information, but PET images provide cardiologists with much more useful information and a clearer image. Rubidium-82, the tracer NCC's application proposes to utilize for cardiac PET imaging, is reported to yield better image quality by suppressing noise in the imaging.[2] Additionally, PET positron emission tracers usually lead to lower radiation exposure than SPECT tracers, mostly attributable to the shorter half-life of PET tracers.[3]

Hospitalizations from CAD for people over the age of 65 occur in moderate numbers in the area surrounding NCC (located approximately where the black dot is placed on the map), as can be seen in **Figure 1**; however, directly south of NCC, the hospitalizations increase fairly drastically. Those over the age of 65 are more likely to be affected by CAD. **Table 1** illustrates the higher rate of population growth in PD 8 compared to Virginia as a whole. The general population in PD 8 is

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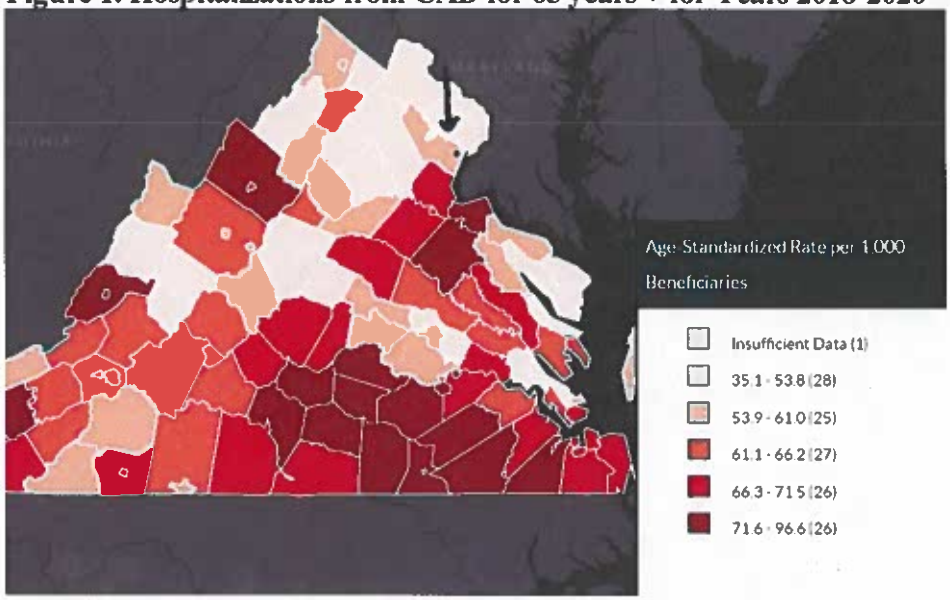
[1] Ghotbi AA, Kjaer A, Hasbak P. Review: comparison of PET rubidium-82 with conventional SPECT myocardial perfusion imaging. Clin Physiol Funct Imaging. 2014 May;34(3):163-70. doi: 10.1111/cpf.12083. Epub 2013 Sep 13. PMID: 24028171; PMCID: PMC4204510.

[2] Ibid

[3] Ibid.

projected to grow at a rate of 13.53% from 2020-2030, while the same group across Virginia is expected to grow at a rate for 7.82% for the same period. Narrowing the perspective, the projected census growth for PD 8 for the 65+ cohort between 2020-2030 is 37.53%, while the average Virginia 65+ cohort is only anticipated to grow at a rate of 27.34%.

Figure 1. Hospitalizations from CAD for 65 years + for Years 2018-2020



Source: nccd.cdc.gov generated map

Table 1. PD 8 Population Data and Projections

Locality	2010	2020	% Change 2010-2020	Avg Ann % Change 2010-2020	2030	% Change 2020-2030	Avg Ann % Change 2020-2030
Arlington	139,966	166,261	18.79%	1.69%	182,067	9.51%	0.91%
Fairfax County	207,627	249,298	20.07%	1.80%	274,339	10.04%	0.96%
Loudoun	22,565	25,047	11.00%	1.02%	26,397	5.39%	0.53%
Prince William	1,081,726	1,162,504	7.47%	0.71%	1,244,025	7.01%	0.68%
Alexandria City	12,332	14,988	21.54%	1.92%	17,032	13.64%	1.29%
Fairfax City	312,311	430,584	37.87%	3.18%	554,808	28.85%	2.57%
Falls Church City	37,821	43,099	13.96%	1.28%	46,332	7.50%	0.73%
Manassas City	14,273	17,086	19.71%	1.77%	20,284	18.72%	1.73%
Manassas Park City	402,002	478,134	18.94%	1.71%	571,844	19.60%	1.81%
Total PD 8	**2,230,623**	**2,587,000**	**15.98%**	**1.46%**	**2,937,128**	**13.53%**	**1.28%**
PD 8 65+	**192,589**	**300,491**	**56.03%**	**4.44%**	**413,269**	**37.53%**	**3.24%**
Virginia	8,001,024	8,655,021	8.17%	0.77%	9,331,666	7.82%	0.76%
Virginia 65+	976,937	1,352,448	38.44%	3.22%	1,723,382	27.43%	2.45%

Source: Weldon-Cooper Census Data

The applicant states in the application to "provide [their] patients with the most technologically advanced and comprehensive cardiovascular care;[their] physicians are Board Certified in Cardiology with subspecialty certifications in areas such as Interventional Cardiology, Electrophysiology, Nuclear Cardiology, Echocardiography, and Peripheral Vascular Disease." Their

aim with this project is to "further expand [their] distinctive cardiovascular care by providing patients in the region with access to the myocardial perfusion imaging (MPI) test, which is generally preferred by patients and practitioners and recommended due to its high diagnostic accuracy, greater interpretive certainty and lower radiation exposure to both patients and staff."

Table 2. PD 8 COPN Authorized PET Units

Facility	Fixed /Mobile	Number of Scanners	Number of Scans	Utilization[7]
Virginia Hospital Center	Fixed	1	767	12.8%
Carient Heart and Vascular	***Fixed***	***1***	***3,185***	***53.1%***
Carient Heart and Vascular-Vienna[1]	***Fixed***	***1***	--	--
Fairfax PET/CT Imaging Center (Inova Center for Personalized Health)	Fixed	1	2,103	35.1%
Nancy Harty (Metro Region PET Center)	Fixed	1	3,417	57.0%
Sentara Northern Virginia Medical Center [2]	Mobile	1	20	3.3%
PET of Reston[3]	Fixed[6]	1	874	14.6%
Kaiser Permanente Woodbridge Imaging Center[4]	Fixed	1	--	--
Virginia Heart[5]	***Fixed***	***1***	--	--
UVA Cancer Center Gainesville (Novant Health)	Mobile	1	510	8.5%
PD 8 Average (all scanners)		**10**	**10,876**	**18.2%**

Source: DCOPN Records and VHI 2021 Data

[1]COPN VA-04825 is expected to become operational April 30, 2023

[2]COPN VA-04629 became operational June 20, 2021

[3]COPN VA-04740 became operational November 15, 2021

[4]COPN VA-04700 became operational September 19, 2022

[5]COPN VA-04806 is expected to become operational March 31, 2023

[6]PET of Reston converted their mobile to a fixed site February 2022

[7]Utilization based on 6,000 scan SMFP threshold

There are 10 PET(/CT) units in PD 20/HPR II, 4 of which are specific to cardiology, ***located*** in **Table 2**. Two of the three cardiac exclusive units are not yet operational but are expected to be in the spring of 2023. PET units are more expensive than SPECT units, but the radiotracers used have vastly different levels of radiation exposure, and the time frame in which to complete the scan itself is significantly different. A cardiac PET scan often uses Rubidium-82, whose half-life is about 75 seconds, while SPECT uses radiotracers that have half-lives of about 6 hours.[4] A cardiac PET scan can take about 30 minutes to complete, while a SPECT scan can take upwards to two hours to complete. The imaging quality in a PET scan image is much better than a SPECT image due to less

[4] https://www.dicardiology.com/article/spect-scanner-vs-pet-which-best#:~:text=While%20PET%20is%20more%20expensive,life%20of%20about%2075%20seconds.

noise in the image, higher spatial resolution, and less artifacts (oddities in the image that can misidentified as perfusion defects).[5]

Proposed Project

NCC proposes to establish PET services with one fixed site Cardiac PET. The specific model being sought is the Siemens ECAT Exact 47 dedicated PET system with cardiac gating. Equipment will be leased from Cardiac Imaging, a corporation in Delaware, whom the applicant reports is "an industry leader specializing in Cardiac PET imaging." Once the applicant has an authorized COPN, they will request the zoning permit needed to proceed with the PET installation. The building is currently zones as O(L), Low Rise Office. The addition of the scanner to the office will require minimal construction/renovation. The scanner will be located in Suite 101, where it will have sufficient space for shielding and to be easily incorporated in the imaging center's current workflow. The PET scanner will be added to an existing structure, therefore, there is no anticipation of needing water, sewer, solid waste additions, or parking expansion.

The expected completion date is 6 months from COPN approval. The applicant has March 2023 as the start of construction with completion as September 2023. May 10, 2023, assuming no IFFC is needed, is the Commissioner's Decision Due Date; using this date, the anticipated completion would be November 2023. (The Code of Virginia § 32.1-102.8. states that if services are provided through a project that is constructed, undertaken, or commenced without a required certificate or registration the provider may be enjoined from providing those services).

The applicant anticipates services being available 8 a.m.-4 p.m., one day per week. NCC foresees no restrictions for participation in the service, unless the patient does not exhibit the clinical indication supporting the medical necessity for the testing. NCC is not anticipating on needing to hire any additional staff as a radiologic technologist is already employed at NCC.

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the "[e]stablishment of a medical care facility described in subsection A… [such as,] [a]ny specialized center or clinic or that portion of a physician's office developed for the provision of outpatient or ambulatory… positron emission tomographic (PET) scanning…"

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

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

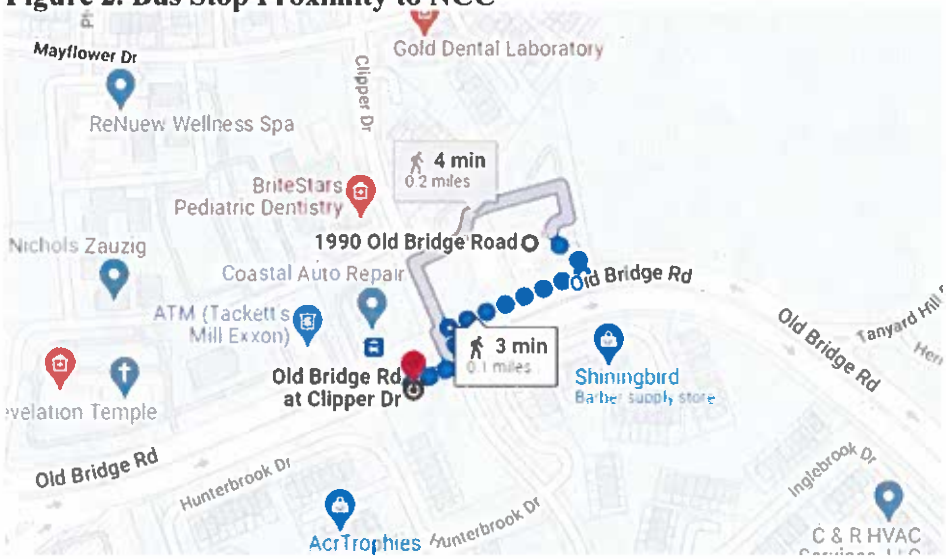
1. **The extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and**

[5] https://www.dicardiology.com/article/spect-scanner-vs-pet-which-best#:~:text=While%20PET%20is%20more%20expensive,life%20of%20about%2075%20seconds.

unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

NCC is located 0.1-0.2 miles walking distance from the Old Bridge Road at Clipper Drive Bus Stop (**Figure 2**). The transportation system in the area is OmniRide and it provides a variety of transportation options depending on individuals' needs to include buses and paratransit options for those with disabilities. Additionally, the office is located within close proximity to Highway 123 and Interstate 95, making the office easily accessible.

Figure 2. Bus Stop Proximity to NCC



Source: DCOPN Generated from Google Maps and Omniride.com

2. **The extent to which the project will meet the needs of the residents of the area to be served, as demonstrated by each of the following:**

(i) The level of community support for the project demonstrated by citizens, businesses, and governmental leaders representing the area to be served.

The applicant provided one letter of endorsement from Cardinal Internal Medicine in Woodbridge, Virginia. The letter endorsed the project stating that NCC is not only trustworthy in delivering quality and cost-appropriate care for their patients, but that NCC is known to not refuse care to patients based upon their ability to pay for services. No letters of opposition were submitted to DCOPN. No letters or statements of opposition were received by DCOPN.

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

HSANV's staff report does not list any reasonable alternatives to the proposed service project that would meet the needs of the population in a less costly, more efficient, or more effective

manner. Carient Heart and Vascular and Virginia Heart are the two current facilities with PET services exclusively for cardiology purposes (three scanners total, with two not yet operational); the other locations are focused on oncological PET needs. While there is no shortage of PET units in the planning district, the specific benefit for cardiology access to PET services for MPI is not adequately encompassed in the SMFP's criteria for the addition of a fixed PET unit.

Furthermore, for comparison of the capital costs for fixed site cardiac PET, Carient Heart and Vascular, P.C.'s project to introduce cardiac PET services authorized by COPN number VA-04642 issued February 19, 2019, had a total capital cost of $534,000, which is relatively comparable to NCC's estimated total capital cost of $648,900.

Maintaining the status quo is an option; the two newest scanners exclusively for cardiac use do not have utilization/procedural volume data to determine the actual need within the PD. However, the applicant notes that other than the recently opened Carient service in Manassas, which is reporting heavy and increasing use, there is no dedicated cardiac PET-CT service in its primary service area (eastern Prince William County and northeastern Stafford County), and that existing PET services serve few cardiovascular patients and are not equipped to offer the myocardial perfusion imaging treatment (MPI) option NOVA CC proposes to offer.

Maintaining the status quo would be less costly but would not be as effective as having more direct access to cardiac PET scanning for MPI within the applicant's service area; the ability to have access to imaging that exposes patients to less radiation while also giving providers much more detailed images appears to outweigh the financial costs associated with the project. Furthermore, the applicant proposes to use the scanner for one day per week, for scanning its own patient population.

(iii) Any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6.

The Health Systems Agency of Northern Virginia (HSANV) Board of Directors reviewed at its January 9, 2023, meeting the COPN application filed by NCC (COPN Req. No. 8654) that seeks authorization to add one fixed PET scanner. The Board voted unanimously (seven in favor) to recommend approval of the application.

The Board bases the recommendation on its review of the application, on the HSANV staff report on the proposal, on the testimony and evidence presented at the January 9, 2023, Board of Directors meeting held on the application, and on several basic findings and conclusions, including:

> "Examination of the application, in the context of COPN planning requirements and authorized local PET imaging capacity and service volumes indicates that:
>
> - There is one operational cardiac PET imaging service in Northern Virginia. The Carient Heart and Vascular service, located in Carient's Manassas, VA office has

high and increasing use. To date it has served relatively few [NCC] patients or other residents of eastern Prince William County.

- Within the last year. Carient and Virginia Heart a large regional cardiology practice, have been authorized to establish cardiac PET imaging services in Fairfax County, VA, bringing the regional PET scanner complement dedicated to cardiac PET imaging to three.
- There is no cardiac PET imaging service in eastern Prince William County or in eastern Stafford County, where NOVA CC is a major provider of cardiovascular care.
- NOVA CC proposes to establish and maintain the service through a lease and an operating contract with a vendor, Cardiac Imaging of Oakbrook Terrace, Illinois. The project does not entail a large capital investment by NOVA CC.
- The projected annual service volume, estimated at about 500 patient scans per year during the first two operating years, appears reasonable and attainable.
- Introducing cardiac PET imaging at NOVA CC, is not likely to affect demand or caseloads at other dedicated cardiac PET imaging services.

Based on these findings, and on the information and argument presented in the application, staff believe the application qualifies for approval.[6]"

There was no public comment presented at the meeting. DCOPN agrees with the HSANV recommendation for approval, and concurs with, and adopts, the attached HSANV staff report and analysis.

(iv) Any costs and benefits of the project.

SPECT is the current modality common to cardiac scanning and serves the same population from which cardiac PET patients will be transitioning; discussion of costs and benefits would be remiss without addressing costs and benefits of the project contrasted with the status quo-continual use of SPECT imaging exclusively. While SPECT is significantly less expensive than cardiac PET for both exams and costs of equipment[7], cardiac PET offers higher resolution and significantly lower radiation exposure than SPECT scanning. Additionally, the time to complete a cardiac PET is approximately 30 minutes, while SPECT can take 2 hours or more.[8] SPECT is noted to be potentially more useful in stress testing as the radiopharmaceutical tracers last longer compared to the shorter half-life of the tracers used in cardiac PET imaging, 6 hours compared to 75 seconds, respectively. Ultimately, it would appear that both SPECT and cardiac PET have strengths and weaknesses that can address differing patient needs; it can be rationally assumed that the rise of cardiac PET use will not create extinguishment of lower cost SPECT use at this time[9].

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[6] HSANV Board Meeting Minutes, January 9, 2023

[7] van der Wall EE. Cost analysis favours SPECT over PET and CTA for evaluation of coronary artery disease: the SPARC study. Neth Heart J. 2014 Jun;22(6):257-8. doi: 10.1007/s12471-014-0558-4. PMID: 24756398; PMCID: PMC4031362.

[8] Digigrad. "SPECT vs. PET Imaging for Cardiology: What Is the Difference." Digirad, August 6, 2020. https://www.digirad.com/spect-vs-pet/.

[9] Ibid.

Moreover, illustrated by Dean Montgomery's report for HSANV:

> "Northern Virginia has ten PET imaging services and more than adequate capacity to meet demand. Neither additional services nor additional capacity is needed. After several years of stagnation, demand is now increasing significantly among oncology focused services but they still have substantial unused capacity. After only two years of operations, Carient Heart and Vascular, reports the second highest service volume in the region and has obtained authorization to expand by adding a second service in central Fairfax County. It is unclear whether the extraordinary growth at the Carient service is an aberration or portends rapid increases in demand at other cardiac PET services. The second Carient service and the recently authorized Virginia Heart service will open within the next year.
>
> NOVA CC proposes to develop a PET service that would be dedicated to cardiac PET imaging. Nearly all of those served would be patients from within its patient base, those who would be likely to obtain a SPECT scan or other diagnostic procedure absent the cardiac PET option.
>
> Given the nature of the project, and the reported high service volume of the Carient service, there is little likelihood that a NOVA CC PET service would affect other programs negatively. If there is a risk to the project it is the self-referral potential inherent in the proposal. Charges and payments for PET imaging are notably higher than for SPECT imaging and most other alternative imaging procedures. The economic incentive to choose PET imaging is evident.
>
> There is a credible argument that fragile, difficult to treat cardiac patients may benefit from PET imaging. The ultimate value of the additional clinical data available from PET scanning, its greater sensitivity and specificity, and the associated potential to reduce diagnostic uncertainty, remains to be proven. But the possibility of reducing the number of unnecessary cardiac interventions cannot be ignored or dismissed lightly. Avoiding the risk, cost and futility of these procedures is a worthy, if illusive, goal."

The higher costs for equipment and operation of cardiac PET reasonably outweigh the reduced diagnostic capability/imaging quality and unnecessary radiation exposure from maintaining the status quo.

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

In 2020, VHI's most recent Charity Care Contribution Report, the mean percentage of charity care provided was 3.4% (**Table 3**). Recent changes to §32.16-102.4B of the Code of Virginia now require DCOPN to place a charity care condition on all applicants seeking a COPN. For this reason, DCOPN recommends that the proposed project, if approved, be subject to a 3.4% charity care condition, to be derived from total cardiac PET services revenues, consistent with the HPR II average. DCOPN again notes that its recommendation includes a provision

allowing for the reassessment of the charity care rate at such time as more reliable data becomes available regarding the full impact of Medicaid expansion in the Commonwealth. While the applicant did not include this in their Pro Forma, it does not appear that the charity care contribution would make their project less financially viable.

Table 3. HPR II 2020 Charity Care Contributions

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

Source: 2020 VHI Data

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

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

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

Part II. Diagnostic Imaging Services
Article 4. Criteria and Standards for Positron Emission Tomography

12VAC5-230-200. Travel time.
PET services should be within 60 minutes driving time one way under normal conditions of 95% of the health planning district using a mapping software as determined by the commissioner.

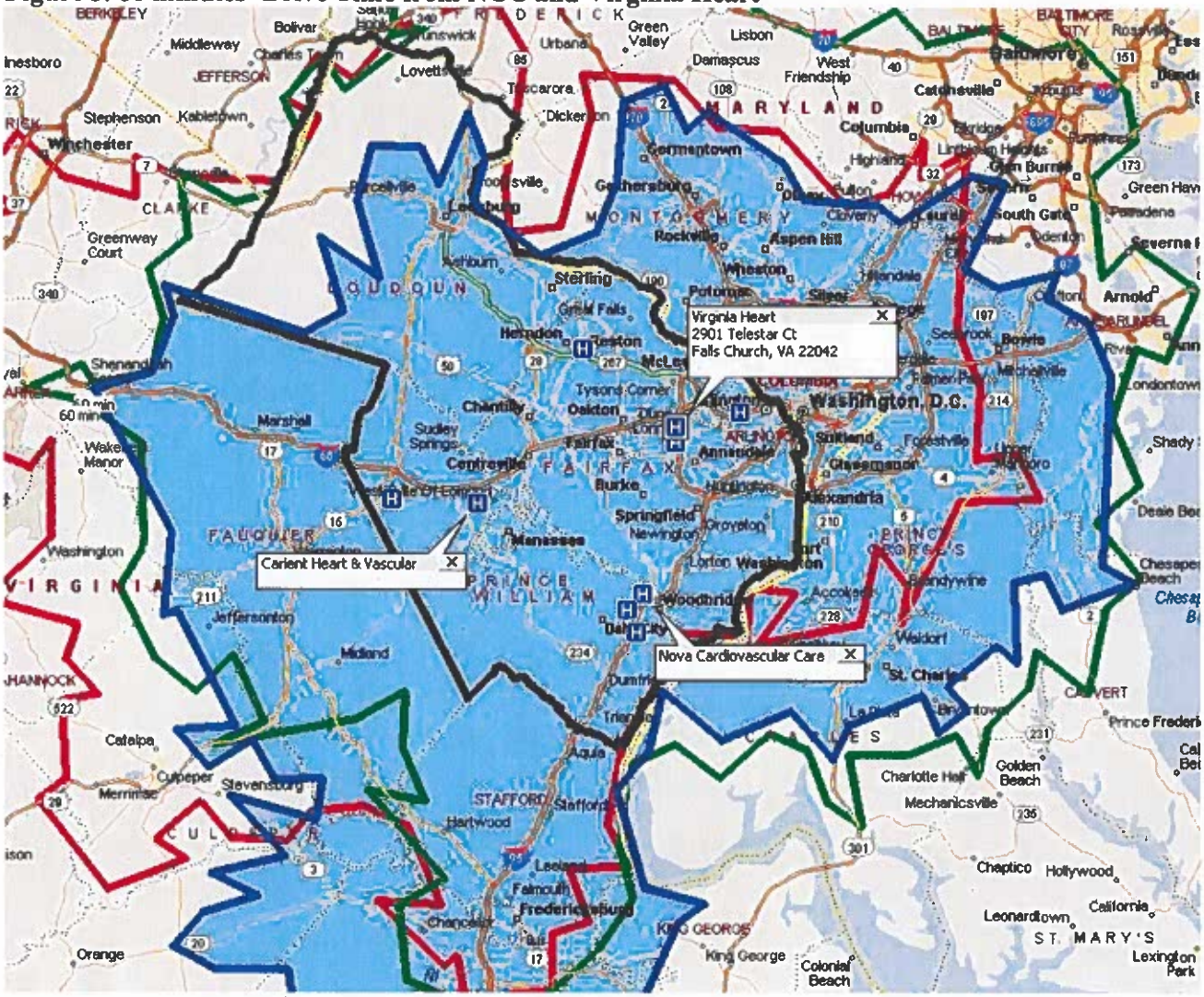
Referencing **Figure 4,** PET, and specifically, cardiac PET services are available to over 95% of the population in PD 8/HPR II within a 60-minutes driving time. The blue shaded and outlined area

represents a 60-minutes driving radius from the proposed location, while the red outline represents a 60-minutes driving radius from Carient Heart & Vascular, and the green outline represents a 60-minutes driving radius from Virginia Heart. The project would not increase geographic access for the PD/HPR as the COPN authorized cardiac-PET units are all within a 60- minutes' drive from 95% or more of the population. Also important to note: Northern Virginia is notorious for having congested traffic conditions, which could impact the drive-time radius[10]. The congestion is normal for the area but impacts driving time at different times of the day and can be heavily impacted in the event of accidents in the area.

It is imperative to consider the cardiac-exclusive nature of the proposed project. As **Table 4** illustrates, Carient Heart & Vascular and Virginia Heart both have Cardiac- exclusive PET and PET/CT, respectively. NCC's location is 39 minutes' drive-time, 18.3 miles, from Carient Heart and Vascular-Manassas and is 30 minutes' drive-time, 18.8 miles, from Virginia Heart.[11] While the SMFP has a standard of services being available within a 60-minute driving distance from 95% of the population, it does not preclude the introduction of services within the geographic area already covered if the public could benefit from the services without a detriment posed to other providers.

[10] Smith, Max. "By the Numbers: Most Congested Types of Roads in Northern Va.." WTOP News, February 28, 2017. https://wtop.com/dc-transit/2017/02/numbers-congested-types-roads-northern-va/.
[11] Distance and time approximated by using Google Maps.

Figure 3. 60 minutes' Drive Time from NCC and Virginia Heart



Source: DCOPN Generated via Microsoft Streets and Trips software

12VAC5-230-210. Need for new fixed site service.

A. If the applicant is a hospital, whether free-standing or within a hospital system, 850 new PET appropriate cases shall have been diagnosed and the hospital shall have provided radiation therapy services with specific ancillary services suitable for the equipment before a new fixed site PET service should be approved for the health planning district.

B. No new fixed site PET services should be approved unless an average of 6,000 procedures per existing and approved fixed site PET scanner were performed in the health planning district during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing fixed site PET providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of PET units in such health planning district.

Note: For the purposes of tracking volume utilization, an image taken with a PET/CT scanner that takes concurrent PET/CT images shall be counted as one PET procedure. Images made with PET/CT scanners that can take PET or CT images independently shall be counted as individual PET procedures and CT procedures respectively, unless those images are made concurrently.

Calculated Needed Fixed PET Scanners in PD 8

COPN authorized fixed PET scanners = 8

Calculated Needed PET scanners =
10,876 scans in the PD / 6,000 scans / scanner = 1.8 (2) scanners needed
PD 8 Calculated Surplus = 6 PET scanners

No PET scanners in 2021, the most recent year with VHI data to use for analysis, performed more than 6,000 procedures within the one year (**Table 4**). In agreement with HSANV's findings, the SMFP is outdated in terms of the 6,000-procedure threshold, especially for the consideration of cardiac PET being a specialized use of the equipment, therefore limiting the quantity of procedures performed on these machines. NCC's proposed cardiac PET would promote geographic availability (when considering the traffic patterns in northern Virginia), would encourage the further use of a facility rather than constructing another, and would not likely undermine the proliferation of services provided by other providers in the area (as NCC is going to use cardiac PET for its own patient pool).

Table 4. PET(/CT) Procedural Volume PD 8 2015-2021

Service	Equipment Type	*Patients/Scans*						
		2015	2016	2017	2018	2019	2020	2021
Carient Heart & Cardiovascular-Manassas[1]	Stationary (Cardiac)						1,793	3,185
Carient Heart & Cardiovascular[3]	Stationary (Cardiac)							
Metro Region PET Center	Stationary	2,492	2,678	2,738	2,592	2,652	2,691	3,417
Fairfax PET-CT Service	Stationary	1,462	1,470	1,257	1,723	1,734	1,797	2,103
UVA Cancer Center Gainsville	Mobile, Part-time	466	463	598	501	475	500	510
PET of Reston	Mobile, Part-time	406	470	615	625	711	700	874
Sentara Northern Virginia Medical Center[1]	Mobile, Part-time							20
Virginia Heart[3]	Stationary (Cardiac)							
Virginia Hospital Center	Stationary	661	798	838	705	895	710	767
Kaiser Foundation Health Plan[2]	Stationary							
Northern Virginia Total		5,487	5,879	6,046	6,146	6,467	8,191	10,876

Source: Annual Serice Volume, Virginia Health Information, ALSD, 2015-2021

[1] Service authorized in 2018 [2] Service authorized in 2019 [3] Service authorized in 2022

Source: HSANV Staff Report regarding COPN Req. VA-8654 via VHI Data

NCC anticipates 20-30% of its SPECT patients would be appropriate for cardiac PET imaging; they report 1,555 SPECT visits in 2021, which would equate to an estimated 311-467 potential cardiac PET imaging patients. Compared to other stationary PET units, NCC would be on the lower end of procedure volume (most closely comparable to Virginia Hospital Center). Using the higher 500 PET appropriate patients yearly estimate, a volume of 9-10 (9.6) patients per scanning day would be expected, in harmony with the contract estimates. Carient Heart and Vascular had a volume of 3,185

PET procedures for 2021, and has their unit available 5 days a week. Assuming 260 working days per year, they would have had to perform approximately 12-13 (12.25) scans per working day.

DCOPN includes the SPECT information in **Table 5** to show that NCC is a competitive and integral provider within the HPR. NCC is proposing to have cardiac PET operating one day per week in order to serve the approximately 20-30% of SPECT appropriate patients who are also cardiac PET appropriate. The contract NCC is proposing to utilize also allows for additional time for scanning if needed. As the HSANV staff report states, the quantity of cardiac PET scans exceeded the estimation Carient Heart and Vascular originally planned for, indicating the need for the service provision within the PD/HPR.

Table 5. 2021PET and SPECT Procedures per Facility within PD8/HPR II

Facility	Units	Class	IP&OP Procedure Quantity/Unit
PET of Reston	1	PET - Mobile	874
Sentara Northern Virginia Medical Center	1	PET - Mobile	20
UVA Cancer Center Gainesville	1	PET - Mobile	510
Fairfax PET/CT Imaging Center	1	PET - Stationary	2,103
Metro Region PET (Nancy Harty)	1	PET - Stationary	3,417
Virginia Hospital Center	1	PET - Stationary	767
Carient Heart and Vascular	1	PET - Stationary	3,185
Inova Alexandria Hospital	1	SPECT	960
Inova Fair Oaks Hospital	2	SPECT	117
Inova Fairfax Hospital	1	SPECT	674
Inova Loudoun Hospital	1	SPECT	400
Inova Mount Vernon Hospital	3	SPECT	165
Metro Region PET Center (Nancy Harty)	2	SPECT	854
Prince William Hospital	1	SPECT	101
Reston Hospital Center	2	SPECT	64
Sentara Northern Virginia Medical Center	1	SPECT	259
Stone Springs Hospital Center	1	SPECT	59
UVA Haymarket Medical Center	1	SPECT	78
Virginia Hospital Center	2	SPECT	1,872

Source: VHI 2021 and DCOPN Inventory Data

In an HSANV memorandum dated November 29, 2022, local market dynamics regarding PET services and specifically the provision of cardiac PET are described. Though PET scanning is the preferred diagnostic tool for many who might benefit from myocardial perfusion imaging, providers of PET services across PD 8 have not taken the steps to support this clinical application until Carient was approved to offer cardiac-specific PET at its Manassas office. Prior to this, cardiologists relied on Single Proton Emission Computer Tomography (SPECT). There is now a shift underway from SPECT to PET as a more beneficial modality for cardiac imaging; with this shift comes the need for increased capacity.

12VAC5-230-220. Expansion of fixed site services.
Proposals to increase the number of PET scanners in an existing PET service should be approved only when the existing scanners performed an average of 6,000 procedures for the

relevant reporting period and the proposed expansion would not significantly reduce the utilization of existing fixed site providers in the health planning district.

Not applicable as the applicant is not proposing to expand fixed site services.

12VAC5-230-230. Adding or expansing mobile PET or PET/CT services.
A. Proposals for mobile PET or PET/CT scanners should demonstrate that, for the relevant reporting period, at least 230 PET or PET/CT appropriate patients were seen and that the proposed mobile unit will not significantly reduce the utilization of existing providers in the health planning district.

B. Proposals to convert authorized mobile PET or PET/CT scanners to fixed site scanners should demonstrate that, for the relevant reporting period, at least 1,400 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing providers in the health planning district.

Not applicable as the applicant is neither proposing to add or expand mobile services or to convert mobile services to fixed services.

12VAC5-230-240. Staffing.
PET services should be under the direction or supervision of one or more qualified physicians. Such physicians shall be designated or authorized by the Nuclear Regulatory Commission or licensed by the Division of Radiologic Health of the Virginia Department of Health, as applicable.

The applicant has provided assurances that the proposed cardiac PET service will be under the direction or supervision of one or more qualified physicians, to include:

Kambiz Yazdani MD, FACC, RPVI
Board Certification(s):
Cardiovascular Disease
Registered Physician in Vascular Interpretation
Nuclear Cardiology

Mohammad M. Ghazvini, MD, FACC, FHRS
Board Certification(s):
Clinical Cardiac Electrophysiology
Cardiovascular Disease

Seyi Bolorunduro,MD MPH FACC, FSCAI
Board Certification(s):
Cardiovascular Diseases
Echocardiography
Interventional cardiology
nuclear cardiology

Vikaas Kataria, MD, FACC, RPVI
Board Certification(s):
Cardiovascular Disease
Registered Physician in Vascular Interpretation
Echocardiography
Nuclear Medicine
Internal Medicine

Furthermore, there is no anticipated need for additional staffing as they have a radiologic technician; staffing needs will not impact other providers in the area.

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

The project would not foster institutional competition as it would be utilizing the PET equipment for a small portion of its own patient population. The project would not increase geographic access with regard to the SMFP 60-minutes driving time for 95% of the population in the PD/HPR, but it would increase access to the service area NCC serves. The Carient Heart and Vascular original PET unit has resulted in higher use than expected, which is anticipated in other locations (Carient Heart and Vascular- Vienna and Virginia Heart). The staff report associated with Carient Heart and Vascular' s Vienna office PET that resulted in COPN-04825 states: "[t]he applicant already offers cardiac PET imaging at its Manassas site, but referral volumes have outstripped its ability to provide the service within reasonable wait times, even after expanding hours and days of operation. Additionally, the proposed new site would decrease travel time for patients residing closer to Vienna than the existing Manassas site." The referral volumes were much higher than anticipated, indicating that the need for this service is significant. While the utilization for the two cardiac PET units will be unknown for some time, the volume for these scanning needs does not go unnoticed. To reiterate, the proposed project also proposes to only operate one day per week for its own patients' needs.

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

The applicant states the cardiac PET patients will come from within its own patient pool of SPECT appropriate patients. As noted above, the proposed quantity of cardiac PET procedures would be comparable to Carient Heart and Vascular, another cardiac PET provider, in terms of ratio of time available to use the equipment. Approval of this project would allow for NCC's own patient pool to have access to an advanced imaging modality that yields more accurate imaging with less radiation exposure for those of whom the advanced imaging modality is appropriate for.

The 30- and 39-minutes' drive time is an estimate during normal driving conditions. As these facilities are all located in northern Virginia, it is imperative to consider the extensive traffic in the area that can greatly affect those estimated times depending on the time of day as well as the sporadic effects of traffic accidents to the transportation infrastructure in Northern Virginia. NCC having a cardiac PET would give patients living in the area the opportunity to utilize the same quality of services closer to their homes. In addition, the age 65+ population in PD 8 is projected to grow faster than in Virginia overall and will likely continue to increase demand for cardiac PET/CT. It is difficult to ascertain for certain whether the two units that have not become operational will be able to handle the referrals from other providers, but both applications have anticipated also serving their own patient population. The initial Carient cardiac-PET volumes indicate that NCC having cardiac PET imaging available one day per week for existing patient population would not likely adversely affect other providers.

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

The total capital cost of construction (**Table 6**) is $648,900. The applicant will be able to pay the costs through the term of the lease and will not require external financing. The applicant is contracting with Cardiac Imaging, Inc. for a lease payment of $7,000 per month, or $84,000 per year, for the PET scanner and maintenance. A separate contract details a payment of $7,500 "per supply day" for radiopharmaceuticals and other supplies and services provided by the vendor. A supply day is determined to be a 9.5-hour day where 1.5 hours are allocated to equipment testing and calibration and 8.0 hours to patient scanning. Additionally, the contract requires one supply day per week (Friday, 52 weeks) during the first year of operation. Operational time required beyond the scheduled supply day would be billed at $800 per hour. Contractual assumptions estimate a service volume of approximately 10 cases per supply day, about one case per operational hour. These arrangements translate to a contractual expense of about $948 per scan.

Table 6. Total Capital Cost for Project VA-8654

Direct Construction Cost	$36,900
Equipment Not Included in Construction Contract	$ 252,000
Site Acquisition Costs	$360,000
Total Capital Cost	**$ 648,900**

Source: COPN Req. No. VA-8654

The project appears to be financially viable in both the short and long term (**Table 6**). The incremental columns in **Table 6** are indicative of the projected revenues and expenses associated with only the project itself. The "Actual" column gives a summary of the entire facility's revenues and expenses before the project approval.

Table 6. COPN Req. No. VA-8654 Pro Forma Summary

	Actual	Year 1 Incremental	Year 2 Incremental	Year 3 Incremental
Total Operating Revenue	$3,952,000	$700,000	$805,000	$925,750
Total Operating Expenses	$4,285,000	$529,600	$542,440	$557,206
Income/(Loss) from Operations	$971,000	$480,400	$619,060	$557,205
Net Income	**$918,000**	**$480,400**	**$619,060**	**$557,205**

Source: COPN Req. VA-8654

7. **The extent to which the project provides improvements or innovations in the financing and delivery of health services, as demonstrated by: (i) The introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services. (ii) The potential for provision of services on an outpatient basis. (iii) Any cooperative efforts to meet regional health care needs. (iv) At the discretion of the Commissioner, any other factors as may be appropriate.**

The proposed project would provide improvements in the delivery of health care services by increasing the provision of cardiac PET scanning services on an outpatient basis. PD 8 has PET(/CT) and cardiac PET(/CT) services (albeit limited for cardiac exclusive services in the area), so the proposed project would not provide improvements or innovations in the financing

and delivery of health care services, as demonstrated by the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services. The applicant does not make any arguments regarding any cooperative efforts to meet regional health care needs. The applicant only provides outpatient services. DCOPN did not identify any other discretionary factors, not discussed elsewhere in this staff analysis report, to bring to the attention of the Commissioner as may be relevant in determining the extent to which the project provides improvements or innovations in the financing and delivery of health services.

8. **In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served.**

   (i) The unique research, training, and clinical mission of the teaching hospital or medical school. (ii) Any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care for citizens of the Commonwealth, including indigent or underserved populations.

   Not applicable. The applicant is not affiliated with a teaching hospital associated with a public institution of higher education or a medical school in the area to be served.

DCOPN Findings

DCOPN finds that the proposed project to establish a new cardiac PET/CT site through the addition of one mobile unit to NCC is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. The applicant proffered that the PET scanner would be used solely for cardiac imaging with the intended patients being derived from their current patient population. While the planning district does not meet the utilization threshold for the establishment of a new service, precedent has been established by the Commissioner regarding this threshold not barring the establishment of new PET services when sufficiently compelling circumstances exist. As such compelling reasons exist, DCOPN recommends that the Commissioner, in this specific instance, not allow this standard to bar the establishment of cardiac PET services at this location.

DCOPN finds that the proposed project is more beneficial than the alternative of the status quo. Under the status quo, patients of NCC will either experience lengthy waits for cardiac PET imaging or will not be able to use the service, requiring a less effective diagnostic imaging modality to be used. With current barriers to access, patients would continue to utilize SPECT imaging, though cardiac PET would better meet their needs. Cardiac PET imaging offers several important advantages over SPECT, including faster imaging, lower dosage of radiation, and better image quality. This last advantage is particularly important as it improves accuracy, risk stratification, and patient selection for interventions.

The HSANV Board voted seven in favor, none opposed to approve NCC's COPN Req. VA-8654. DCOPN finds the total capital cost of the project to be reasonable and the project to be financially viable in both the short and long term.

DCOPN Staff Recommendations

The Division of Certificate of Public Need recommends the **conditional approval** of Nova Cardiovascular Care, Inc.'s COPN Request No. VA-8654 to establish a medical care facility for cardiac PET imaging for the following reasons:

1. The proposal is generally consistent with the applicable standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia.

2. There benefits of the project to the public outweigh the costs of the project.

3. The capital costs of the proposed project are reasonable.

4. The PET scanner's use will be limited solely to cardiac imaging.

5. The proposed project appears to be financially viable in the immediate and long-term.

6. The Health Systems Agency of Northern Virginia recommended approval of the proposed project.

7. There is no known opposition to the project.

DCOPN's recommendation is **contingent** upon Nova Cardiovascular Care, Inc.'s agreement to the following **condition**:

Nova Cardiovascular Care, Inc. will provide cardiac positron emission tomography (PET) services to all persons in need of this service, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and facilitate the development and operation of primary care services to medically underserved persons in an aggregate amount equal to at least 3.4% of Nova Cardiovascular Care, Inc.'s total patient services revenue derived from PET services as valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. Compliance with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement. Nova Cardiovascular Care, Inc. will accept a revised percentage based on the regional average after such time regional charity care data valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. is available from Virginia Health Information. The value of charity care provided to individuals pursuant to this condition shall be based on the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.

Nova Cardiovascular Care, Inc. will provide PET services to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et seq. Additionally, Nova

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