

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

July 21, 2025

RE: COPN Request No. VA-8813

Carent Heart & Vascular, LLC
Manassas, Virginia

Introduce CT imaging for calcium scoring using the CT portion of the PET/CT

COPN Request No. VA-8814

Carent Heart & Vascular, LLC
Vienna, Virginia

Introduce CT imaging for calcium scoring using the CT portion of the PET/CT

Applicant

COPN Request No. VA-8813: Carent Heart & Vascular, LLC -Manassas

Carent Heart & Vascular, LLC (“Carent”) is a Virginia limited liability company. Carent is wholly owned by US Health Virginia, LLC. The location of the proposed project is Carent’s office in Manassas, Virginia in Planning District (PD) 8, Health Planning Region (HPR) II.

COPN Request No. VA-8814: Carent Heart & Vascular, LLC -Vienna

Carent Heart & Vascular, LLC (“Carent”) is a Virginia limited liability company. Carent is wholly owned by US Health Virginia, LLC. The location of the proposed project is Carent’s office in Vienna, Virginia in Planning District (PD) 8, Health Planning Region (HPR) II.

Background

Carent is seeking authorization to utilize the CT component of existing PET/CT scanners, one each at its Manassas and Vienna offices, independently for Coronary Artery Calcium (CAC) Scoring. According to Carent’s applications (COPN Request Nos. VA-8813 & VA-8814) traditional risk assessment models, like cholesterol levels and blood pressure measurements, do not fully capture cardiovascular risk. “CAC scoring is a non-invasive, low-dose CT scan that detects and quantifies calcified plaque in the coronary arteries. This diagnostic tool is instrumental in assessing the risk of coronary artery disease (CAD)...CAC provides direct, quantifiable evidence of coronary atherosclerosis, enabling physicians to tailor preventive and therapeutic strategies more effectively.” Each of Carent’s two proposed sites has a PET/CT scanner in operation. No capital cost or additional equipment is required to implement the proposed projects.

Table 1. PD 8 CT Utilization, 2023 VHI

Facility Name	Facility Type	CT Scanners	Total CT Procedures	% of SMFP Threshold
ED - Inova Emergency Room - Ashburn HealthPlex	Freestanding ED	1	11,058	149.4%
ED - Inova Emergency Room - Fairfax City	Freestanding ED	1	5,521	74.6%
ED - Inova Emergency Room - Franconia Springfield HealthPlex	Freestanding ED	1	19,129	258.5%
ED - Inova Emergency Room - Leesburg	Freestanding ED	1	13,576	183.5%
ED - Inova Emergency Room - Lorton HealthPlex	Freestanding ED	1	11,133	150.4%
ED - Sentara Lake Ridge	Freestanding ED	1	5,406	73.1%
ED - Tysons Emergency (RHC)	Freestanding ED	1	2,707	36.6%
Fair Oaks Imaging Center	Freestanding	1	2,981	40.3%
Fairfax ENT & Facial Plastic Surgery	Freestanding	1	658	8.9%
Fairfax Radiology Center at Prosperity	Freestanding	1	9,245	124.9%
Fairfax Radiology Center of Centreville	Freestanding	1	9,719	131.3%
Fairfax Radiology Center of Fairfax City	Freestanding	1	6,955	94.0%
Fairfax Radiology Center of Lansdowne	Freestanding	1	8,737	118.1%
Fairfax Radiology Center of Reston-Herndon	Freestanding	1	7,829	105.8%
Fairfax Radiology Center of Sterling	Freestanding	1	6,328	85.5%
Inova Alexandria Hospital	Acute Hospital	3	50,467	227.3%
Inova Fair Oaks Hospital	Acute Hospital	3	46,144	207.9%
Inova Fairfax Hospital	Acute Hospital	7	137,138	264.7%
Inova Imaging Center-Mark Center	Freestanding	1	4,426	59.8%
Inova Loudoun Hospital	Acute Hospital	2	54,275	366.7%
Inova Mount Vernon Hospital	Acute Hospital	2	26,164	176.8%
Insight Imaging - Arlington	Freestanding	1	3,130	42.3%
Insight Imaging - Fairfax	Freestanding	1	4,475	60.5%
Kaiser Permanente - Reston Medical Center	Freestanding	1	7,188	97.1%
Kaiser Permanente - Tyson's Corner	Freestanding	2	20,489	138.4%
Kaiser Permanente - Woodbridge Imaging Center	Freestanding	1	15,558	210.2%
Kaiser Permanente - Woodbridge Surgery Center	Amb Surgery	1	15,558	210.2%
Kaiser Permanente Tysons Corner Surgery Center	Amb Surgery	2	20,489	138.4%
Lakeside @ Loudoun Tech Center 1	Freestanding	1	32	0.4%
LMG Imaging Center	Freestanding	1	708	9.6%
Orthopaedic Foot and Ankle Center of Washington	Freestanding	1	89	1.2%
Reston Hospital Center	Acute Hospital	4	38,468	130.0%
Sentara Advanced Imaging Center - Alexandria	Freestanding	1	-	0.0%
Sentara Advanced Imaging Center - Lake Ridge	Freestanding	1	3,928	53.1%
Sentara Northern Virginia Medical Center	Acute Hospital	3	28,970	130.5%
Stone Springs Hospital Center	Acute Hospital	1	9,118	123.2%
Tysons Corner Diagnostic Imaging	Freestanding	1	970	13.1%
Tysons MRI and Imaging Center	Freestanding	1	4,901	66.2%
UVA Health Haymarket Medical Center	Acute Hospital	1	11,586	156.6%
UVA Health Prince William Medical Center	Acute Hospital	2	22,111	149.4%
UVA Outpatient Imaging Centreville	Freestanding	1	1,444	19.5%
Virginia Cancer Specialists	Freestanding	1	854	11.5%
Virginia Hospital Center	Acute Hospital	5	52,514	141.9%
Woodburn Diagnostic Center	Freestanding	2	13,442	90.8%
PD 8 CT Totals and Average		69	715,618	140.2%

Source: 2023 VHI

According to Virginia Health Information (VHI), 69 CT scanners were operational in PD 8 in 2023, the latest year for which such data are available. The CT scanners were well utilized at 140.2% of

the State Medical Facilities Plan (SMFP) standard of 7,400 CT scans per scanner (**Table 1**). Since 2023 data were reported to VHI, twelve additional CT scanners were authorized in PD 8 (See **Table 2** and footnotes), so PD 8 now has 81 CT scanners. In addition to these CT scanners, there are currently eight PET/CT scanners in PD 8 that are restricted to cardiac use, and of those, two utilize the CT component separately for calcium scoring. These are not included in the inventory of CT units in **Table 2**.

Table 2. PD 8 COPN Authorized Fixed CT Units

Facility	# of Scanners
Centreville-Clifton Imaging Center - Fairfax Radiology	1
Chantilly ER ¹	1
Fair Oaks Imaging Center	1
Fairfax Diagnostic Imaging Center	1
Fairfax ENT & Plastic Surgery Center	1
Fairfax MRI and Imaging Center at Tysons	1
Fairfax Radiology Center at Prosperity	2
Fairfax Radiology Center of Reston-Herndon	1
Fairfax Radiology Center of Springfield ²	1
Fairfax Radiology Center at Woodburn	2
Inova Alexandria Hospital ³	4
Inova Ashburn Healthplex	1
Inova Emergency Room of Fairfax City	1
Inova Emergency Room of Reston/Herndon ⁴	1
Inova Fair Oaks Hospital	3
Inova Fairfax Hospital ⁵	8
Inova Health Center – Woodbridge ⁶	1
Inova HealthPlex - Franconia/Springfield	1
Inova Imaging Center – Leesburg	1
Inova Imaging Center-Mark Center	1
Inova Lorton HealthPlex	1
Inova Loudoun Hospital	3
Inova Mount Vernon Hospital	2
Inova Oakville Ambulatory Center in the City of Alexandria	1
Inova Springfield Hospital ⁷	1
Kaiser Permanente - Reston Medical Center	1
Kaiser Permanente - Tysons Corner Imaging Center	2

¹ COPN No. VA-04900 authorized Northern Virginia Hospital, LLC to establish CT services with one CT unit at Chantilly ER.

² COPN No. VA-04878 authorized IFRC, LLC to establish CT services with one CT unit at Fairfax Radiology Center of Springfield. The project is expected to be completed by October 1, 2024.

³ COPN No. VA-04793, issued July 7, 2022, authorized the addition of one fixed CT scanner at the relocated Inova Alexandria Hospital (Landmark).

⁴ COPN No. VA-04921 authorized the re-establishment of CT services at Inova Emergency Room Reston/Herndon.

⁵ COPN No. VA-04922 authorized the 8th CT scanner at Inova Fairfax Hospital.

⁶ COPN No. VA-04896 authorized IFRC, LLC to establish CT services with one CT unit at Inova Health Center – Woodbridge.

⁷ COPN No. VA-04832 authorized the relocation and replacement of Inova Alexandria, including the addition of one CT scanner.

Facility	# of Scanners
Kaiser Permanente - Woodbridge Imaging Center	1
Leesburg Emergency and Imaging Center ⁸	1
Loudoun Medical Group, P.C.	1
Metropolitan ENT & Facial Plastic Surgery	1
Orthopaedic Foot and Ankle Center	1
Radiology Imaging Associates at Lansdowne	1
Radiology Imaging Associates at Sterling ⁹	1
Rayus Radiology - Arlington (formerly known as Insight Imaging - Arlington)	1
Rayus Radiology - Fairfax	1
Rayus Radiology - Woodbridge ¹⁰	1
Reston Hospital Center	4
Sentara Advanced Imaging Center - Alexandria	1
Sentara Lake Ridge Ambulatory Care Center	1
Sentara Northern Virginia Medical Center	2
Sentara Northern Virginia Medical Center - Century Medical Office Building	1
StoneSprings Hospital Center	2
Tysons Corner Emergency Center	1
Tysons Corner Diagnostic Imaging	1
UVA Outpatient Imaging – Gainesville ¹¹	1
UVA Outpatient Imaging - Centreville	1
UVA Health Haymarket Medical Center	1
UVA Health Prince William Medical Center	2
VHC Emergency & Imaging Center ¹²	1
VHC Health Outpatient Imaging Center ¹³	1
Virginia Hospital Center	4
Washington Radiology Associates	1
Woodburn Nuclear Medicine/Metro Region PET	1
Total	81

Source: DCOPN records

⁸ COPN No. VA-04863 authorized Reston Hospital Center, LLC to establish a specialized center for CT imaging, Leesburg Emergency and Imaging Center. The project is expected to be completed by November 30, 2025.

⁹ COPN No. VA-04931 authorized the relocation of the CT scanner at Radiology Imaging Associates at Sterling to introduce CT at IFRC – Ballston, expected complete in June 2026.

¹⁰ COPN No. VA-04879 authorized Insight Health Corporation to establish CT services with one CT unit at Rayus Radiology – Woodbridge. The project is expected to be completed by October 31, 2024.

¹¹ COPN No. VA-04906 authorized UVA Outpatient Imaging Centreville, LLC to establish a specialized center for the provision of CT services with one CT unit. The project is expected to be completed by April 30, 2026.

¹² COPN No. VA-04775 authorized VHC to establish a specialized center for CT imaging at VHC Emergency and Imaging Center with one CT scanner. VHC Emergency and Imaging Center is expected to open in the fourth quarter of 2024.

¹³ COPN No. VA-04880 authorized Virginia Hospital Center Arlington Health System d/b/a VHC Health to establish a specialized center for CT and MRI with one CT unit and one MRI unit. The project is expected to be completed by June 16, 2025.

Proposed Project

Carent has existing PET/CT scanners at both the Manassas and the Vienna locations, and it proposes to use the CT component of each PET/CT scanner for the limited purpose of stand-alone CAC scoring. CAC scoring to assess cardiovascular risk entails using the CT component of the PET/CT system independent of the PET element. There is no capital cost involved in either project since no modifications are needed, and the PET/CT scanners are already in place. The applicant can begin seeing patients at each of the two proposed sites upon receipt of a COPN.

COPN Request No. VA-8813: Carent-Manassas

The location of Carent's PET/CT unit in the City of Manassas is 8100 Ashton Avenue, Suite 200, Manassas, Virginia.

COPN Request No. VA-8813: Carent-Vienna

The location of Carent's PET/CT unit in the town of Vienna in Fairfax County is 415 Church Street, NE, Suite 101, Vienna, Virginia.

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the “[i]ntroduction into an existing medical care facility described in subsection A of any...computed tomographic (CT) scanning...” A medical care facility includes “[a]ny specialized center or clinic or that portion of a physician’s office developed for the provision of ... 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 unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.**

PD 8 is a large and fast-growing area of Virginia, estimated to grow to 2.8 million people, adding nearly 280,000 people between 2020 and 2030. This projected growth of 10.9% for PD 8 in the current decade is nearly twice the growth rate projected for Virginia at 5.8% (**Table 3**). **Figure 1** is a map of the localities in PD 8 and shows Manassas City and Vienna (within Fairfax County), where the proposed projects are located. The number of people over 65 is expected to grow by nearly 98,000 people in PD 8 between 2020 and 2030, through in-migration and aging. This is 32% growth, compared to Virginia’s projected growth of 26.3% for the 65+ segment during the same period (**Table 3**).

Table 3. Population by Locality, PD 8

Locality	2020 Population	2030 Projected Population	Projected Growth 2020-2030	Percent Growth 2020-2030	65+ 2020 Population	Projected 65+ 2030 Population	Projected Growth 65+	Percent Growth 65+
Arlington Co.	238,643	265,794	27,151	11.4%	25,333	28,501	3,168	12.5%
Fairfax Co.	1,150,309	1,201,420	51,111	4.4%	158,687	195,132	36,445	23.0%
Loudoun Co.	420,959	522,015	101,056	24.0%	41,497	65,844	24,347	58.7%
Prince William Co.	482,204	554,344	72,140	15.0%	50,522	76,112	25,590	50.7%
Alexandria City	159,467	176,403	16,936	10.6%	18,758	22,941	4,183	22.3%
Fairfax City	24,146	25,358	1,212	5.0%	3,871	4,726	855	22.1%
Falls Church City	14,658	16,741	2,083	14.2%	2,185	2,545	360	16.5%
Manassas City	42,772	47,039	4,267	10.0%	4,505	6,593	2,088	46.4%
Manassas Park City	17,219	19,876	2,657	15.4%	1,343	2,162	819	61.0%
PD 8	2,550,377	2,828,990	278,613	10.9%	306,701	404,555	97,854	31.9%
Virginia, Statewide	8,631,393	9,129,002	497,609	5.8%	1,395,291	1,762,641	367,350	26.3%

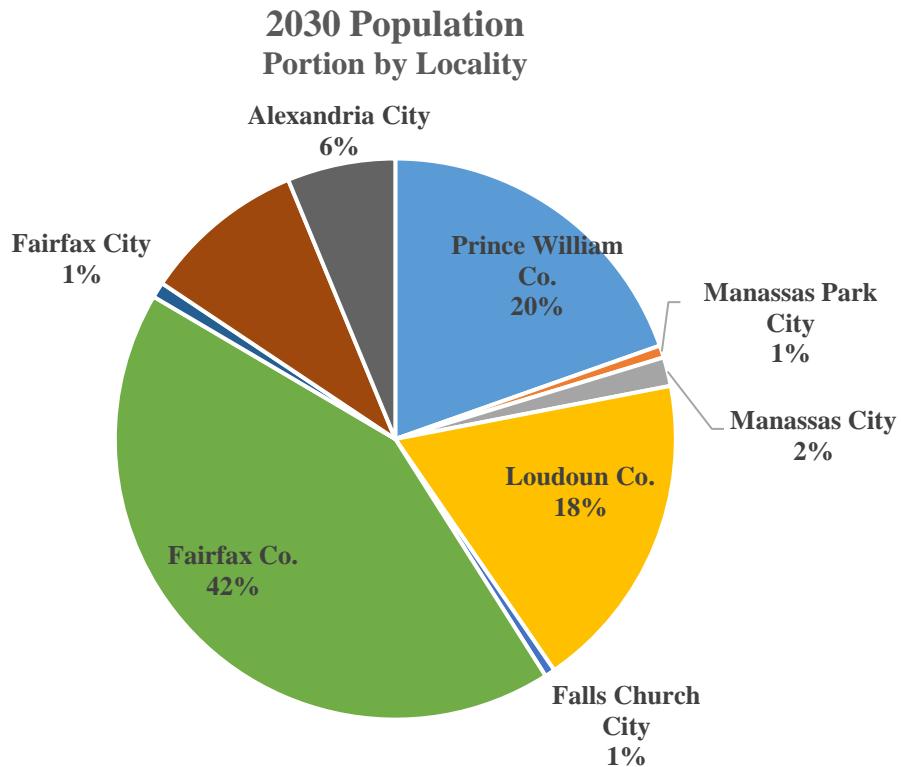
Sourced from U.S. Census Bureau at <https://data.census.gov/> and Weldon Cooper Center for Public Service, August 2023.

Figure 1. Map of PD 8 Localities



Manassas City is expected to represent 2% of residents of PD 8 by 2030 and Fairfax County 42% (Figure 2).

Figure 2



Sourced from United States Census Bureau at <https://data.census.gov/> and Weldon Cooper Center for Public Service, August 2023.

COPN Request No. VA-8813: Carent Heart & Vascular, LLC -Manassas

Patients are able to access the proposed facility from Virginia Route 234, and it is located less than two miles from Exit 47 on Interstate 66. OmniRide's Manassas Local North route provides public transportation access Monday through Friday. Manassas City has the highest poverty rate of localities in PD 8, though still lower than the poverty rate in Virginia (**Table 4**). No unique socioeconomic, transportation or other barriers are identified.

COPN Request No. VA-8814: Carent Heart & Vascular, LLC -Vienna

Patients can access Carent's Vienna office by car or public transportation. It is 3.2 miles from Exit 16 on VA-267 (Dulles Toll Road), 2.3 miles from Exit 46A on Interstate 495 and 2 miles from Tysons Corner. It is 2.3 miles and 3.1 miles, respectively, from Tysons Corner and Vienna metro stations. The Fairfax Connector bus service runs multiple routes daily to the Maple Avenue/Beulah Road and Maple Avenue/East Street stops (0.1 miles and 0.3 miles, respectively, from Carent's office in Vienna. Fairfax County, in which Vienna is located, has a relatively low poverty rate, 5.9%, much lower than Virginia's average poverty rate and lower than the PD 8 poverty rate (**Table 4**). No unique socioeconomic, transportation or other barriers are identified.

Table 4. 2022 Poverty Rates, PD 8

Locality	% in Poverty
Arlington County	6.8%
Fairfax County	5.9%
Loudoun County	3.8%
Prince William County	6.9%
Alexandria City	9.0%
Fairfax City	7.6%
Falls Church City	4.1%
Manassas City	9.1%
Manassas Park City	8.9%
PD 8	6.1%
Virginia	10.6%

Source: US Census Bureau, Small Area Income and Poverty Estimates

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.

COPN Request No. VA-8813: Carent Heart & Vascular, LLC -Manassas

DCOPN received a statement of intent signed by twenty-one Carent physicians in support of the proposed project. It also received two other letters of support from area physicians. These letters, in aggregate, expressed the following:

- Carent Heart & Vascular is a multi-specialty cardiovascular practice with 17 board-certified cardiologists, 3 vascular surgeons and 16 advanced practice providers.
- Carent has eight locations across Northern Virginia and has been serving the community for over 20 years.
- The non-invasive imaging service will significantly enhance the early detection and risk stratification of coronary artery disease, improving patient outcomes while reducing health care costs.
- Carent is committed to quality CAC scoring studies, ensuring patients receive accurate and timely diagnoses to guide optimal treatment decisions.
- The addition of CAC scoring aligns with our mission to provide cost-effective, patient-centered care, reducing unnecessary invasive procedures and improving risk assessment for patients with suspected coronary artery disease.
- Coronary artery disease remains the leading cause of morbidity and mortality in Virginia and across the nation.

- The proposed project will enhance the continuum of care and help prevent adverse cardiac events through early interventions and targeted preventive measures.
- I frequently encounter patients without access to advanced diagnostic tools such as CAC scoring.
- Early detection is key in preventing cardiovascular disease and CAC scoring is an invaluable tool for assessing a patient's risk.
- Many patients with risk factors such as hypertension or a family history of heart disease could greatly benefit from this non-invasive test. The ability to access CAC scoring within our community would enable better-informed treatment decisions and improve patient outcomes.
- Expanded access to CAC scoring will bridge a critical gap in preventive cardiology and help identify patients who need early intervention before experiencing cardiac events.

COPN Request No. VA-8814: Carent Heart & Vascular, LLC -Vienna

DCOPN received a statement of intent signed by twenty-one Carent physicians in support of the proposed project. It also received two letters of support from other area physicians. These letters, in aggregate, expressed the following:

- Carent Heart & Vascular is a multi-specialty cardiovascular practice with 17 board-certified cardiologists, 3 vascular surgeons and 16 advanced practice providers.
- Carent has eight locations across Northern Virginia and has been serving the community for over 20 years.
- The non-invasive imaging service will significantly enhance the early detection and risk stratification of coronary artery disease, improving patient outcomes while reducing health care costs.
- Carent is committed to quality CAC scoring studies, ensuring patients receive accurate and timely diagnoses to guide optimal treatment decisions.
- The addition of CAC scoring aligns with our mission to provide cost-effective, patient-centered care, reducing unnecessary invasive procedures and improving risk assessment for patients with suspected coronary artery disease.
- Coronary artery disease remains the leading cause of morbidity and mortality in Virginia and across the nation.
- The proposed project will enhance the continuum of care and help prevent adverse cardiac events through early interventions and targeted preventive measures.
- I frequently encounter patients without access to advanced diagnostic tools such as CAC scoring.
- Early detection is key in preventing cardiovascular disease and CAC scoring is an invaluable tool for assessing a patient's risk.
- Many patients with risk factors such as hypertension or a family history of heart disease could greatly benefit from this non-invasive test. The ability to access CAC scoring within our community would enable better-informed treatment decisions and improve patient outcomes.
- Expanded access to CAC scoring will bridge a critical gap in preventive cardiology and help identify patients who need early intervention before experiencing cardiac events.

Public Hearings

COPN Request No. VA-8813: Carent Heart & Vascular, LLC -Manassas &
COPN Request No. VA-8814: Carent Heart & Vascular, LLC -Vienna

§32.1-102.6B of the Code of Virginia directs DCOPN to hold one public hearing on each application in the case of competing applications or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. Public hearings were held at the monthly meeting of the Health Systems Agency of Northern Virginia on June 9, 2025.

DCOPN provided notice to the public regarding these projects inviting public comment on May 15, 2025. The public comment period closed on June 29, 2025. Other than the letters of support referenced above, no members of the public commented. There is no known opposition to either project.

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

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The proposals seek to provide a non-invasive assessment of myocardial perfusion and viability using CAC scoring, a tool that provides direct visualization of arterial plaque and allowing for more precise risk stratification, early intervention and improved patient management. As both Carent sites already have authorized and operational PET/CT systems, CAC scoring can be offered using the CT component of the system independently at no capital cost. Furthermore, the applicant proposes to use the PET/CT units in their respective locations to serve its existing patient population, so DCOPN concludes that the proposed projects are unlikely to adversely affect the utilization and efficiency of existing services. No alternative has been identified that meets the needs of the population in a less costly, more efficient or more effective manner. The proposed project is more beneficial than the status quo.

(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.

HSANV considered the proposed projects at its June 9, 2025 meeting.

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At its June 9, 2025 meeting, the HSANV, the organization in HPR II designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 8, voted nine in favor, none opposed, to recommend approval of Carent Heart & Vascular, LLC's COPN Request number VA-8813. The HSANV based its recommendation on its review of the application, on the HSANV staff report on the proposal, on the information presented at the June 9, 2025 public hearing and Board of Directors meeting, and on several basic findings and conclusions, including:

1. Though not endorsed by the U.S. Preventive Services Task Force (USPSTF), coronary artery calcium (CAC) scoring is increasingly viewed as a diagnostic imaging test useful in the identification of disease and assessment of risk of adverse cardiac events.
2. Carent is authorized to operate two cardiac PET services with CT scanning capability.
3. CAC scoring can be introduced using existing PET/CT scanners and operating personnel without additional capital investment.
4. There is no indication that adding CAC scoring at Carent's cardiac PET services, or at other cardiac programs with PET/CT systems, would affect other services negatively.
5. The Virginia State Medical Facilities Plan (SMFP) does not contain planning guidance specific to the utility of coronary artery calcium scoring in cardiovascular disease diagnostic and treatment. The project is generally consistent with the principles and policies on which the plan is based.

COPN Request No. VA-8814: Carent Heart & Vascular, LLC -Vienna

At its June 9, 2025 meeting, the HSANV, the organization in HPR II designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 8, voted nine in favor, none opposed, to recommend approval of Carent Heart & Vascular, LLC's COPN Request number VA-8814. The HSANV based its recommendation on its review of the application, on the HSANV staff report on the proposal, on the information presented at the June 9, 2025 public hearing and Board of Directors meeting, and on several basic findings and conclusions, including:

1. Though not endorsed by the U.S. Preventive Services Task Force (USPSTF), coronary artery calcium (CAC) scoring is increasingly viewed as a diagnostic imaging test useful in the identification of disease and assessment of risk of adverse cardiac events.
2. Carent is authorized to operate two cardiac PET services with CT scanning capability.
3. CAC scoring can be introduced using existing PET/CT scanners and operating personnel without additional capital investment.
4. There is no indication that adding CAC scoring at Carent's cardiac PET services, or at other cardiac programs with PET/CT systems, would affect other services negatively.
5. The Virginia State Medical Facilities Plan (SMFP) does not contain planning guidance specific to the utility of coronary artery calcium scoring in cardiovascular disease diagnostic and treatment. The project is generally consistent with the principles and policies on which the plan is based.

(iv) Any costs and benefits of the project.

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There is no capital cost associated with the proposed projects. They entail the use of the CT component of operational PET/CT systems independently for CAC scoring. CAC scoring is a cost-effective, evidence-based tool for detection of early cardiovascular disease. Its use helps aid physicians in treatment planning of coronary artery disease, the leading cause of morbidity and mortality in Virginia and across the nation. The applicant states, "The cost of CAC screening is relatively low compared to the potential costs associated with treating heart attacks or other major

cardiovascular events. While not universally covered by insurance, CAC scoring is cost-effective...and reduces the need for more expensive interventions down the line.” CAC scoring can reduce the need for hospital admissions, emergency interventions and long-term treatments. The proposed projects are expected to improve patient outcomes.

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

According to regional and statewide data regularly collected by VHI, for 2023, the most recent year for which such data are available, the average amount of charity care provided by HPR II facilities was 1.9% of all reported total gross patient revenues (**Table 5**).

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The proforma provided by the applicant (**Table 6**) includes an estimated 5.6% charity care as a percentage of patient revenue, exceeding the most recently available HPR II average. In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project receive approval, the project would be conditioned to provide a level of charity care based on gross patient revenues derived from CAC scoring, in this case, the 5.6% proffered in the proforma provided. Pursuant to Code of Virginia language any COPN issued for this project will also be conditioned on the applicant’s agreement to accept patients who are the recipients of Medicare and Medicaid.

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The proforma provided by the applicant (**Table 7**) includes an estimated 5.6% charity care as a percentage of patient revenue, exceeding the most recently available HPR II average. In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project receive approval, the project would be conditioned to provide a level of charity care based on gross patient revenues derived from CAC scoring, in this case, the 5.6% proffered in the proforma provided. Pursuant to Code of Virginia language any COPN issued for this project will also be conditioned on the applicant’s agreement to accept patients who are the recipients of Medicare and Medicaid.

Table 5. HPR II Charity Care Contributions: 2023

HPR II	Gross Pt Rev	Total Charity Care Provided Below 200%	%
Encompass Health Rehab Hosp of Northern Virginia	\$ 47,006,703	\$ 1,815,624	3.9%
Sentara Northern Virginia Medical Center	\$ 1,045,324,552	\$ 36,160,381	3.5%
Inova Alexandria Hospital	\$ 1,429,207,087	\$ 37,429,423	2.6%
Inova Mount Vernon Hospital	\$ 763,866,669	\$ 18,931,409	2.5%
Inova Fairfax Hospital	\$ 6,178,801,539	\$ 147,787,884	2.4%
Inova Loudoun Hospital	\$ 1,401,069,976	\$ 30,988,208	2.2%
Virginia Hospital Center	\$ 2,186,532,064	\$ 46,172,024	2.1%
Inova Fair Oaks Hospital	\$ 1,066,144,047	\$ 22,481,850	2.1%
Dominion Hospital	\$ 186,176,170	\$ 2,045,071	1.1%
Reston Hospital Center	\$ 2,138,632,642	\$ 17,987,554	0.8%
StoneSprings Hospital Center	\$ 539,217,793	\$ 3,146,642	0.6%
North Spring Behavioral Healthcare	\$ 81,326,336	\$ 341,453	0.4%
UVA Health Prince William Medical Center	\$ 635,237,781	\$ 0	0.0%
UVA Health Haymarket Medical Center	\$ 367,868,585	\$ 0	0.0%
Total Inpatient Hospitals:			14
HPR II Total Inpatient \$ & Mean %	\$ 18,066,411,944	\$ 65,287,523	2.0%
HealthQare Services ASC, LLC	\$ 12,393,083	\$ 933,007	7.5%
Stone Springs Ambulatory Surgery Center	\$ 42,421,176	\$ 774,214	1.8%
Northern Virginia Eye Surgery Center, LLC	\$ 16,978,280	\$ 45,760	0.3%
Lake Ridge Ambulatory Surgical Center	\$ 12,789,859	\$ 30,788	0.2%
Haymarket Surgery Center	\$ 62,445,476	\$ 88,885	0.1%
Reston Surgery Center	\$ 165,980,869	\$ 37,296	0.0%
Northern Virginia Surgery Center	\$ 63,630,227	\$ 13,450	0.0%
McLean Ambulatory Surgery Center	\$ 46,154,897	\$ 7,660	0.0%
Inova Loudoun Ambulatory Surgery Center	\$ 98,462,265	\$ 15,163	0.0%
Inova Surgery Center @ Franconia-Springfield	\$ 99,121,487	\$ 7,799	0.0%
Fairfax Surgical Center	\$ 170,498,365	\$ 2,356	0.0%
Prince William Ambulatory Surgery Center	\$ 58,808,176	\$ 0	0.0%
Kaiser Permanente Tysons Corner Surgery Center	\$ 48,527,291	\$ 0	0.0%
Kaiser Permanente Caton Hill Ambulatory Surgery Center	\$ 21,993,825	\$ 0	0.0%
Inova Ambulatory Surgery Center at Lorton	\$ 8,494,696	\$ 0	0.0%
Pediatric Specialists of Virginia Ambulatory Surgery Center	\$ 7,412,957	\$ 0	0.0%
Total Outpatient Hospitals:			16
HPR II Total Outpatient Hospital \$ & Mean %	\$ 936,112,929	\$ 1,956,378	0.2%
Total Hospitals:			30
HPR II Total Hospital \$ & Mean %	\$ 19,002,524,873	\$ 367,243,901	1.9%

Source: VHI (2023)

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

There are no other factors, not addressed elsewhere in the analysis, relevant to the determination of a public need for either project.

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

Section 32.1-102.2:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop recommendations for a comprehensive State Health Services Plan (SHSP). In the interim, DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the State Medical Facilities Plan (SMFP).

The SMFP contains criteria/standards for the establishment or expansion of CT services. They are as follows:

**Part II Article 1
Diagnostic Imaging Services
Criteria and Standards for Computed Tomography**

12VAC5-230-90. Travel time.

CT services should be available within 30 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the commissioner.

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COPN Request No. VA-8814: Carent Heart & Vascular, LLC -Vienna

The CT portions of the existing PET/CT units at the respective proposed sites will be used for CAC scoring and not for any other diagnostic CT imaging. CAC scoring to assess cardiovascular risk entails using the CT component of the PET/CT system independent of the PET element. Access to diagnostic CT services will not be affected by approval of the proposed projects.

12VAC5-230-100. Need for new fixed site or mobile service.

A. No new fixed site or mobile CT service should be approved unless fixed site CT services in the health planning district performed an average of 7,400 procedures per existing and approved CT scanner during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of CT scanners in such health planning district.

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COPN Request No. VA-8814: Carent Heart & Vascular, LLC -Vienna

The CT portion of the existing PET/CT units will be used for CAC scoring and not for any other diagnostic CT imaging. Furthermore, Carent intends for the tool to be provided to its existing patient base. Thus, approval of the proposed project will have no effect on the utilization of existing providers of diagnostic CT units in PD 8. DCOPN includes the information below, however, to present a full picture of the existing CT inventory and diagnostic needs in PD 8.

DCOPN notes that several CT scanners have been added to the PD 8 inventory since the preparation of the 2023 VHI data as displayed in **Table 1**. **Table 2** displays the current inventory of CT scanners in PD 8.

As noted in **Table 1**, in 2023, the utilization of existing CT scanners in the planning district was 140.2% of the average procedures per scanner necessary to introduce CT scanning services to a new location under this section of the SMFP. Moreover, DCOPN calculates a need for sixteen additional fixed CT scanners in the planning district.

Calculated Needed Fixed CT Scanners in PD 8

Calculated Needed CT scanners = 715,618 scans in PD 8 in 2023 / 7,400 scans = 96.7 (97) scanners needed

PD 8 Calculated Need = 97 CT scanners based on 2023 utilization data

2025 COPN authorized CT scanners = 81

PD 8 Calculated Deficit = 16 CT scanners

B. Existing CT scanners used solely for simulation with radiation therapy treatment shall be exempt from the utilization criteria of this article when applying for a COPN. In addition, existing CT scanners used solely for simulation with radiation therapy treatment may be disregarded in computing the average utilization of CT scanners in such health planning district.

DCOPN has excluded existing CT scanners used solely for simulation prior to the initiation of radiation therapy from its inventory and average utilization of diagnostic CT scanners in PD 8.

12VAC5-230-110. Expansion of fixed site service.

Proposals to expand an existing medical care facility's CT service through the addition of a CT scanner should be approved when the existing services performed an average of 7,400 procedures per scanner for the relevant reporting period. The commissioner may authorize placement of a new unit at the applicant's existing medical care facility or at a separate location within the applicant's primary service area for CT services, provided the proposed expansion is not likely to significantly reduce the utilization of existing providers in the health planning district.

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COPN Request No. VA-8814: Carent Heart & Vascular, LLC -Vienna

Not applicable. The applicant is not seeking to expand CT services at either proposed site.

12VAC5-230-120. Adding or expanding mobile CT services.

A. Proposals for mobile CT scanners shall demonstrate that, for the relevant reporting period, at least 4,800 procedures were performed and that the proposed mobile unit will not significantly reduce the utilization of existing CT providers in the health planning district.

B. Proposals to convert authorized mobile CT scanners to fixed site scanners shall demonstrate that, for the relevant reporting period, at least 6,000 procedures were

performed by the mobile CT scanner and that the proposed conversion will not significantly reduce the utilization of existing CT providers in the health planning district.

COPN Request No. VA-8813: Carent Heart & Vascular, LLC -Manassas &
COPN Request No. VA-8814: Carent Heart & Vascular, LLC -Vienna

Not applicable. The applicant does not propose to add or expand mobile CT services or to convert authorized mobile CT scanners to fixed site scanners.

12VAC5-230-130. Staffing.

CT services should be under the direction or supervision of one or more qualified physicians.

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COPN Request No. VA-8814: Carent Heart & Vascular, LLC -Vienna

The applicant confirmed that the proposed CT services would be under the direct supervision of qualified physicians.

Required Considerations Continued

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.

COPN Request No. VA-8813: Carent Heart & Vascular, LLC -Manassas &
COPN Request No. VA-8814: Carent Heart & Vascular, LLC -Vienna

The proposed projects do not foster beneficial institutional competition. CAC scoring studies performed by the CT component of existing PET/CT systems at the respective proposed sites will be performed on Carent's existing patient base.

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.

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Carent Heart & Vascular is a multi-specialty cardiovascular practice with 17 board-certified cardiologists, 3 vascular surgeons and 16 advanced practice providers. It has eight locations across Northern Virginia. Three of these offer PET services. Based upon CT procedure volumes in 2023 and the current inventory of authorized CT scanners, 16 additional CT scanners are needed in PD 8; however, the proposal does not add to the inventory of diagnostic CT scanners in the PD.

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.

COPN Request No. VA-8813: Carent Heart & Vascular, LLC -Manassas

There is no capital cost associated with the proposed project and no additional staffing required to provide CAC scoring on the CT component of the existing PET/CT unit. The applicant projects a net income of \$53,340 the first year and \$56,100 the second year (**Table 6**). The proposal is fully feasible in the immediate and long-term.

Table 6. Carent Heart & Vascular, LLC -Manassas

	Year 1	Year 2
Total Gross Patient Revenue¹⁴	\$59,400	\$59,400
Charity Care	\$3,300	\$3,300
Net Revenue	\$56,100	\$56,100
Total Expenses	\$2,760	\$0
Net Income	\$53,340	\$56,100

Source: COPN Request No. VA-8813

COPN Request No. VA-8814: Carent Heart & Vascular, LLC -Vienna

There is no capital cost associated with the proposed project and no additional staffing required to provide CAC scoring on the CT component of the existing PET/CT unit. The applicant projects a net income of \$53,340 the first year and \$56,100 the second year (**Table 7**). The proposal is fully feasible in the immediate and long-term.

Table 7. Carent Heart & Vascular, LLC -Vienna

	Year 1	Year 2
Total Gross Patient Revenue¹⁵	\$59,400	\$59,400
Charity Care	\$3,300	\$3,300
Net Revenue	\$56,100	\$56,100
Total Expenses	\$2,760	\$0
Net Income	\$53,340	\$56,100

Source: COPN Request No. VA-8814

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.

COPN Request No. VA-8813: Carent Heart & Vascular, LLC -Manassas &
COPN Request No. VA-8814: Carent Heart & Vascular, LLC -Vienna

¹⁴ The applicant provided a range of gross patient revenue in COPN Request No. VA-8813 completeness responses. DCOPN used an average of the top and bottom of the range.

¹⁵ The applicant provided a range of gross patient revenue in COPN Request No. VA-8814 completeness responses. DCOPN used an average of the top and bottom of the range.

The proposals would bring the relatively new tool of CAC scoring to PD8 where it is not yet widely available. This is a tool that enables early diagnosis and better treatment planning for patients with coronary artery disease. The proposals also allow for delivery of care in outpatient facilities. No cooperative efforts are noted by the applicant.

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.

COPN Request No. VA-8813: Carent Heart & Vascular, LLC -Manassas &
COPN Request No. VA-8814: Carent Heart & Vascular, LLC -Vienna

Not applicable. These facilities are 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 Staff Findings and Conclusions

COPN Request No. VA-8813: Carent Heart & Vascular, LLC - Manassas

The proposed project is in a highly populated and fast-growing area of the Commonwealth. DCOPN finds that the proposed project to introduce a CT service by utilizing the CT portion of the existing PET/CT unit independently at Carent Heart & Vascular, LLC's Manassas office is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. PD 8 meets the utilization threshold for the establishment of a new CT service, though the proposed project does not add a diagnostic CT scanner to the PD, and the applicant intends that the CT portion of its PET/CT scanner would be restricted to coronary artery calcium (CAC) scoring. Furthermore, the services will be used primarily for Carent's existing patient base and will not affect utilization of existing providers.

DCOPN finds that the proposed project is more beneficial than the alternative of the status quo. Under the status quo, patients of Carent will continue not to have access to a cost-efficient tool that promises early detection and better management of coronary artery disease that improves patient outcomes. The HSANV Board voted nine in favor, none opposed to recommend approval of Carent's COPN Request number VA-8813. There is no capital cost or additional staffing associated with implementation of the proposed project. There is no opposition to the proposal.

COPN Request No. VA-8814: Carent Heart & Vascular, LLC -Vienna

The proposed project is in a highly populated and fast-growing area of the Commonwealth. DCOPN finds that the proposed project to introduce a CT service by utilizing the CT portion of the existing PET/CT unit independently at Carent Heart & Vascular, LLC's Vienna office is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. PD 8 meets the utilization threshold for the establishment of a new CT service, though the proposed project does not add a diagnostic CT scanner to the PD, and the applicant intends that the CT portion of its PET/CT scanner would be

restricted to coronary artery calcium (CAC) scoring. Furthermore, the services will be used for Carent's existing patient base and will not affect utilization of existing providers.

DCOPN finds that the proposed project is more beneficial than the alternative of the status quo. Under the status quo, patients of Carent will continue not to have access to a cost-efficient tool that promises early detection and better management of coronary artery disease that improves patient outcomes. The HSANV Board voted nine in favor, none opposed to recommend approval of Carent's COPN Request number VA-8814. There is no capital cost or additional staffing associated with implementation of the proposed project. There is no opposition to the proposal.

DCOPN Staff Recommendations

COPN Request No. VA-8813: Carent Heart & Vascular, LLC - Manassas

The Division of Certificate of Public Need recommends **conditional approval** of Carent Heart & Vascular, LLC's COPN Request number VA-8813 to introduce a CT service by utilizing the CT portion of the existing PET/CT unit independently in Manassas, Virginia for the following reasons:

1. The proposal to introduce a CT service by utilizing the CT portion of the existing PET/CT unit independently at Carent Heart & Vascular, LLC's office in Manassas is consistent with the applicable standards and criteria of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.
2. The CT service is restricted to coronary artery calcium scoring.
3. There is no capital cost associated with the project.
4. The proposed project is unlikely to have a significant negative impact upon the utilization, costs, or charges of other providers of CT services in PD 8.
5. The proposed project is viable in the immediate and long-term.
6. HSANV recommended approval of the proposed project.
7. There is no known opposition to the project.

DCOPN's recommendation is contingent upon Carent Heart & Vascular, LLC's agreement to the following charity care condition:

Carent Heart & Vascular, LLC will provide CT imaging services (restricted to coronary artery calcium scoring) 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 will facilitate the development and operation of primary medical care services to medically underserved persons in PD 8 in an aggregate amount equal to at least 5.6% of Carent Heart & Vascular, LLC's gross patient revenue derived from CT services at its Manassas location. 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. Carent Heart & Vascular, LLC will accept the revised charity condition based on 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 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.

Carent Heart & Vascular, LLC will provide CT imaging services (restricted to coronary artery calcium scoring) 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, Carent Heart & Vascular, LLC will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.

COPN Request No. VA-8814: Carent Heart & Vascular, LLC -Vienna

The Division of Certificate of Public Need recommends **conditional approval** of Carent Heart & Vascular, LLC's COPN Request number VA-8814 to introduce a CT service by utilizing the CT portion of the existing PET/CT unit independently in Vienna, Virginia for the following reasons:

1. The proposal to introduce a CT service by utilizing the CT portion of the existing PET/CT unit independently at Carent Heart & Vascular, LLC's office in Vienna is consistent with the applicable standards and criteria of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.
2. The CT service is restricted to coronary artery calcium scoring.
3. There is no capital cost associated with the project.
4. The proposed project is unlikely to have a significant negative impact upon the utilization, costs, or charges of other providers of CT services in PD 8.
5. The proposed project is viable in the immediate and long-term.
6. HSANV recommended approval of the proposed project.
7. There is no known opposition to the project.

DCOPN's recommendation is contingent upon Carent Heart & Vascular, LLC's agreement to the following charity care condition:

Carent Heart & Vascular, LLC will provide CT imaging services (restricted to coronary artery calcium scoring) 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 will facilitate the development and operation of primary medical care services to medically

underserved persons in PD 8 in an aggregate amount equal to at least 5.6% of Carent Heart & Vascular, LLC's gross patient revenue derived from CT services at its Vienna location. 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. Carent Heart & Vascular, LLC will accept the revised charity condition based on 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 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.

Carent Heart & Vascular, LLC will provide CT imaging services (restricted to coronary artery calcium scoring) 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, Carent Heart & Vascular, LLC will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.