

**VIRGINIA DEPARTMENT OF HEALTH**  
**Office of Licensure and Certification**  
**Division of Certificate of Public Need**

**Staff Analysis**

September 18, 2024

**COPN Request No. VA-8766**

Centra Health, Inc.

Lynchburg, Virginia

Add a PET/CT at Lynchburg General Hospital for Cardiac Imaging

**Applicant**

Centra Health, Inc. (Centra) is a 501(c)(3) not-for-profit, non-stock corporation located in Lynchburg, Virginia. Centra is the sole owner and operator of Centra Lynchburg General Hospital (Lynchburg General). Lynchburg General is located in the city of Lynchburg, Health Planning Region (HPR) III, Planning District (PD) 11.

**Background**

Cardiac positron emission tomography/computed tomography (PET/CT) is a non-invasive state-of-the-art technology and standard of care for routine cardiac diagnostic imaging. According to the applicant:

“[c]ardiac PET/CT has emerged as the state-of-the-science diagnostic tool for coronary artery disease. The American Society of Nuclear Cardiology (ASNC) and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) released a consensus statement in 2016 stating that PET was recommended and preferred over SPECT when performing myocardial perfusion imaging due to its many advantages including high diagnostic accuracy, low total radiation exposure, fast protocols, and cost effectiveness.” And “PET/CT imaging has become the gold standard for cardiac imaging. In addition to replacing old SPECT technology which produces lower quality images while subjecting patients to higher radiation levels and long procedure times, PET/CT has become the preferred diagnostic tool for patients presenting to the emergency department with chest pain or other symptoms indicating a potential cardiac event. The enhanced sensitivity and specificity of PET/CT images results in both (i) fewer false positives and therefore fewer unnecessary cardiac catheterizations, and (ii) fewer false negatives and therefore cases of untreated cardiovascular disease. By adding a cardiac PET/CT scanner to the Stroobants Cardiovascular Center, Centra will be able to provide the advantages of this diagnostic imaging modality to its community and patients.”

Centra Health is the only provider of PET/CT services in PD 11 with one PET/CT unit at the Centra Alan B. Pearson Regional Cancer Center (Cancer Center). The unit at the Cancer Center is entirely dedicated to oncological imaging and performed 1,124 scans in 2022.

### **Proposed Project**

The applicant proposes to expand PET/CT services by adding one PET/CT unit on the campus of Lynchburg General at the Stroobants Cardiovascular Center. The project will require renovating the existing nuclear medicine space within the center, including the configuration of additional cardiology office space and refurbishment of the EKG and echocardiograph reading rooms. The PET/CT unit will be used exclusively for cardiac studies. The new unit will be a Siemens Biograph mCT Flow edge unit. The applicant currently operates one PET/CT unit at Lynchburg General. However, due to the unique needs of cardiac patients undergoing PET/CT studies, the existing PET/CT services in the Cancer Center cannot meet the applicant’s needs for cardiac PET/CT services. For example, the PET/CT at the Cancer Center is not equipped to perform cardiac PET/CT. Additionally, oncology PET procedures and cardiac PET procedures use different isotopes. The applicant asserts that the CT functionality of the proposed PET/CT scanner will not be utilized independent of the PET functionality.

Centra recently announced a multi-year modernization initiative that will encompass the most significant facility improvements in Centra’s 36-year history. The first phase of the modernization is the revitalization of Lynchburg General. The next phase includes ongoing internal modernization and space reallocation to ensure that Lynchburg General can meet the comprehensive needs of its patients.

The projected capital costs of the proposed project are \$4,076,814, approximately 36% of which are attributed to direct construction costs (**Table 1**). Capital costs will be funded through the accumulated reserves of the applicant. If the State Health Commissioner (Commissioner) approves the project, construction is expected to begin 12 weeks after COPN approval and is projected to be complete six months later. The target date of opening is October, 2025.

**Table 1. Centra Projected Capital Costs**

Direct Construction Costs	\$1,471,352
Equipment Not Included in Construction Contract	\$2,344,969
Architectural and Engineering Fees	\$122,630
Other Consultant Fees	\$137,863
<b>Total Capital Costs</b>	<b>\$4,076,814</b>

Source: COPN Request No. VA-8766

### **Project Definitions**

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the “[t]he addition by an existing medical care facility described in subsection A of any new medical equipment for the provision of “...positron emission tomographic (PET) scanning...” A medical care facility includes “Any facility licensed as a hospital...”

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

In determining whether a public need for a project exists, the following factors shall be considered:

- 1. The extent to which the proposed project will provide or increase access to health care services for people in the area to be served and the effects that the proposed project will have on access to health care services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to health care;**

Geographically, Lynchburg General is located at 1901 Tate Springs Road, Lynchburg, Virginia. According to the applicant, Lynchburg General’s campus is easily accessible by major arterial streets in Lynchburg City and from US Route 29, US Route 501, US Route 460 and US Route 221. Specifically, the Lynchburg General campus is accessible via Langhorne Road from Tate Springs Road, or Atherholt Road. Langhorne Road and Tate Springs Road are both modern, four-lane thoroughfares with traffic lights. Public transportation is provided by the Greater Lynchburg Transit Company and is available to patients with multiple stops per day on the hospital campus.

The population in PD 11 was 261,593 in 2020 and is projected to grow by 1.9% to 266,674 by 2030 (**Table 2**). This is a smaller growth rate than the 5.8% projected for Virginia during the 2020 to 2030 decade. Lynchburg is projected to grow 2.9%, by the end of the decade, by about 2,300 people (**Table 2**). Due to their central location in the PD and the rurality of the surrounding counties, Centra’s Lynchburg-based facilities draw patients widely from across PD 11.

PD 11’s 65 and older population is projected to grow by 19.6% in the 2020 to 2030 decade, less than Virginia with a projected growth rate of 26.3% (**Table 2**). PD 11 is projected to have more than 10,000 additional residents aged 65+ by 2030 than it did in 2020 (**Table 2**).

**Table 2. Population Projections for PD 11, 2020-2030**

Locality	2020	2030	Population Change 2020-2030	Percent Change	2020 Aged 65 and up	2030 Aged 65 and up	Population Change 2020-2030 Aged 65 & up	Percent Change Aged 65 and up
Amherst County	31,307	29,827	-1,480	-4.7%	6,754	7,833	1,079	16.0%
Appomattox County	16,119	17,018	899	5.6%	3,358	4,019	661	19.7%
Bedford County	79,462	82,822	3,360	4.2%	17,848	22,924	5,076	28.4%
Campbell County	55,696	55,739	43	0.1%	11,599	13,501	1,902	16.4%
Lynchburg City	79,009	81,268	2,259	2.9%	12,833	14,399	1,566	12.2%
<b>PD 11</b>	<b>261,593</b>	<b>266,674</b>	<b>5,081</b>	<b>1.9%</b>	<b>52,392</b>	<b>62,677</b>	<b>10,285</b>	<b>19.6%</b>
<b>Virginia</b>	<b>8,631,393</b>	<b>9,129,002</b>	<b>497,609</b>	<b>5.8%</b>	<b>1,395,291</b>	<b>1,762,641</b>	<b>367,350</b>	<b>26.3%</b>

Source: Weldon Cooper, data update August 2023

PD 11 has a poverty rate of 13.2%. higher than that of Virginia at 10.6%, and Lynchburg City’s poverty rate of 19.6% is the highest of the localities in PD 11 and much higher than Virginia’s. (Table 3).

**Table 3. Poverty Rates 2022<sup>1</sup>**

Locality	Poverty Rate
Amherst	12.8%
Appomattox	12.0%
Bedford	8.4%
Campbell	12.7%
Lynchburg City	19.6%
<b>PD 11</b>	<b>13.2%</b>
Virginia	10.6%

According to regional and statewide data regularly collected by VHI, for 2022, the most recent year for which such data is available, the average amount of charity care provided by HPR III facilities was 0.6% of all reported total gross patient revenues (Table 4). If the Commissioner approves the proposed project, DCOPN recommends a charity care condition of no less than the 0.6% HPR III average, in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

**Table 4. HPR III Charity Care Contributions: 2022**

2022 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	% of Gross Patient Revenue:
Rehabilitation Hospital of Bristol, LLC	\$17,981,903	\$504,759	2.8%
Centra Specialty Hospital	\$48,716,727	\$1,120,485	2.3%
Carilion Franklin Memorial Hospital	\$216,535,912	\$4,076,850	1.9%
Carilion Tazewell Community Hospital	\$84,561,982	\$1,031,972	1.2%
Carilion Giles Memorial Hospital	\$182,762,966	\$2,056,398	1.1%
Carilion Medical Center	\$4,626,293,362	\$48,146,682	1.0%
Carilion New River Valley Medical Center	\$908,326,659	\$8,974,962	1.0%
LewisGale Hospital-Montgomery	\$945,286,546	\$6,043,431	0.6%
LewisGale Hospital - Alleghany	\$259,238,606	\$1,552,971	0.6%
LewisGale Hospital Pulaski	\$465,079,395	\$2,565,485	0.6%
Lewis-Gale Medical Center	\$2,945,087,457	\$16,161,621	0.5%
Centra Health	\$3,023,784,179	\$10,182,695	0.3%
Smyth County Community Hospital	\$214,723,312	\$630,654	0.3%

<sup>1</sup> The latest poverty data available are for 2022: [https://www.census.gov/data-tools/demo/saipe/#/?s\\_state=51&s\\_county=51009,51011,51515,51019,51031,51680&s\\_district=&s\\_geography=county](https://www.census.gov/data-tools/demo/saipe/#/?s_state=51&s_county=51009,51011,51515,51019,51031,51680&s_district=&s_geography=county)

<b>2022 Charity Care Contributions at or below 200% of Federal Poverty Level</b>			
<b>Hospital</b>	<b>Gross Patient Revenues</b>	<b>Adjusted Charity Care Contribution</b>	<b>% of Gross Patient Revenue:</b>
Bedford Memorial Hospital	\$175,626,005	\$474,228	0.3%
Norton Community Hospital	\$291,775,554	\$767,018	0.3%
Russell County Medical Center	\$135,556,168	\$330,439	0.2%
Dickenson Community Hospital	\$28,125,420	\$68,308	0.2%
Johnston Memorial Hospital	\$826,084,738	\$1,856,940	0.2%
Wellmont Lonesome Pine Mountain View Hospital	\$779,003,003	\$1,458,898	0.2%
Lee County Community Hospital	\$35,910,227	\$49,714	0.1%
Buchanan General Hospital	\$116,385,318	\$140,702	0.1%
DLP Twin County Regional Healthcare	\$255,330,355	\$293,349	0.1%
Sovah Health-Martinsville	\$677,045,264	\$349,080	0.1%
Clinch Valley Medical Center	\$656,673,348	\$293,630	0.0%
Sovah Health-Danville	\$932,808,724	\$86,078	0.0%
Wythe County Community Hospital	\$292,907,698	\$18,259	0.0%
Ridgeview Pavilion (Bristol Region)	\$7,807,715	--	0.0%
Total Facilities Reporting			27
<b>Median</b>			<b>0.3%</b>
<b>Total \$ &amp; Mean %</b>	<b>\$19,149,418,543</b>	<b>\$109,235,608</b>	<b>0.6%</b>
Fairlawn Surgery Center, LLC	\$6,266,686	\$86,972	1.4%
Surgery Center of Lynchburg	\$71,978,392	\$650,781	0.9%
Roanoke Ambulatory Surgical Center	\$41,399,758	\$364,061	0.9%
Southwest Virginia Center for Sight	\$1,713,979	\$11,841	0.7%
Roanoke Valley Center for Sight	\$22,241,535	\$107,090	0.5%
Roanoke Valley Center for Sight at Oak Grove	\$4,952,855	\$22,821	0.5%
Roanoke Valley Center for Sight at Martinsville	\$5,105,196	\$21,245	0.4%
New River Valley Surgery Center	\$14,607,399	\$48,984	0.3%
Eye Surgery Center of Central Virginia, LLC	\$8,979,556	\$11,400	0.1%
Blue Ridge Surgery Center	\$106,092,378	\$25,571	0.0%
Piedmont Day Surgery Center	\$3,368,071	--	0.0%
Total Outpatient Hospitals:			11
<b>HPR III Outpatient Hospital Median</b>			<b>0.5%</b>
<b>HPR III Total Outpatient Hospital \$ &amp; Mean %</b>	<b>\$286,705,805</b>	<b>\$1,350,766</b>	<b>0.5%</b>
Total Hospitals:			<b>38</b>
<b>HPR III Hospital Median</b>			<b>0.3%</b>
<b>HPR III Total Hospital \$ &amp; Mean %</b>	<b>\$19,436,124,348</b>	<b>\$110,586,374</b>	<b>0.6%</b>

Source: VHI (2022)

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

**(i) the level of community support for the proposed project demonstrated by people, businesses, and governmental leaders representing the area to be served;**

DCOPN received 14 letters of support for the proposed project, which addressed:

- Centra Health has a nationally known cardiovascular program. With Centra Health's expanded service area and capabilities, the health system is positioned to be able to make a difference in the lives of so many people facing cardiac disease in the community.
- The cardiac PET/CT equipment is needed to expand the local capacity for the testing and improve access to care.
- Adding a second PET/CT at Lynchburg General and dedicating the unit to cardiovascular imaging would be a great benefit to not only Lynchburg, but the entire Centra Health service area which spans an area of geography roughly the size of the state of New Jersey.
- The greater Lynchburg market has a high preponderance of cardiovascular disease and a high incidence of obesity, which leads to difficult imaging.
- Cardiac PET/CT is the imaging procedure of choice to rule out cardiac sarcoidosis, which can lead to fatal arrhythmias and cardiomyopathy.
- Many patients with defibrillators and pacemakers cannot have cardiac MRI and therefore PET/CT scanning can provide an excellent way to assess for myocardial ischemia or viability.
- The diagnostic yield of cardiac PET/CT is much better than SPECT, and radiation exposure is much more limited.
- More and more providers across the Commonwealth have recognized the importance of [cardiac PET/CT] and have sought and received COPN approval to establish a dedicated cardiac PET/CT program.
- The current PET/CT at Lynchburg General is dedicated to oncology patients. Furthermore, the scanner is already very busy, with an almost full schedule.
- Lynchburg General operates the only emergency department in the Lynchburg area. As a result, the hospital sees nearly 40,000 emergency department visits, many of which are for cardiovascular care, requiring follow up imaging, inpatient care and/or surgery, and later likely outpatient monitoring.

### Public Hearing

DCOPN provided notice to the public regarding these projects on July 10, 2024. The public comment period closed on August 26, 2024. Section 32.1-102.6 B of the Code of Virginia directs DCOPN to hold one public hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city 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. COPN Request No. VA-8766 is not competing with another project in this batch cycle and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing was held.

**(ii) the availability of reasonable alternatives to the proposed project that would meet the needs of the people in the area to be served in a less costly, more efficient, or more effective manner;**

DCOPN did not identify any reasonable alternatives to the proposed project that would meet the needs of the population in a less costly, more efficient, or more effective manner. Moreover, the proposed project is a preferable alternative to the status quo. Under the status quo, patients in PD 11 will continue to receive cardiac diagnostic imaging using SPECT. As discussed in detail throughout this staff analysis report, cardiac PET/CT imaging offers several important advantages over SPECT. The American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging have issued a joint Society Position Statement “to highlight the attributes that make rest/stress myocardial perfusion PET both **Preferred** and **Recommended** in the era of high value initiative for appropriate patients.”<sup>2</sup> According to this Society Position Statement, “[m]yocardial perfusion PET image quality, high diagnostic accuracy that is relatively independent of body habitus, ability to accurately risk stratify patients with a wide array of clinical presentations, short acquisition times, safety by virtue of low radiation exposure, and its unique ability to quantify myocardial blood flow are all significant and clinically important properties.”<sup>3</sup>

Furthermore, the applicant proposes to use the scanner to serve its existing patient population. Therefore, DCOPN concludes that the proposed project is unlikely to adversely affect the utilization and efficiency of existing services.

**(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;**

Currently there is no organization in HPR III designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 11. Therefore, this consideration is not applicable to the review of the proposed project.

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<sup>2</sup> Bateman et.al. *American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET*. Journal of nuclear cardiology (2016): official publication of the American Society of Nuclear Cardiology. <https://pubmed.ncbi.nlm.nih.gov/27528255/> (accessed March 5, 2024).

<sup>3</sup> Id.

**(iv) any costs and benefits of the proposed project;**

As demonstrated by **Table 1**, the projected capital costs of the proposed project are \$4,076,814, approximately 36% of which are attributed to direct construction costs. Capital costs will be funded through the accumulated reserves of the applicant. DCOPN concludes that when compared to similar projects, these costs are reasonable. For example, COPN No. VA-04874 issued to University of Virginia Medical Center to establish a specialized center for PET with one PET/CT unit is anticipated to cost approximately \$4,000,000.

The applicant identified numerous benefits of the proposed project, including:

- The addition of cardiac PET/CT will further Centra's mission by providing patients with access to superior, high quality cardiovascular imaging technology.
- Co-location of the new PET/CT with existing cardiology diagnostic services will facilitate operational efficiencies, particularly patient flow efficiencies.
- With the location of the PET/CT unit within the four walls of the hospital, emergency room patients who need cardiac PET/CT services can be rapidly and easily transported to the Stroobants Center, thus conserving costs of transportation.
- With heart disease being the leading cause of death in the United States, the Stroobants Cardiovascular Center is dedicated to the prevention, diagnosis and treatment of heart and vascular conditions, and is committed to providing the most advanced, comprehensive cardiovascular care to its patients and the residents of central Virginia. To fulfill this commitment to its community, Centra is seeking approval to expand cardiac PET/CT services by adding a dedicated, fixed PET/CT scanner to the array of diagnostics services currently available at the Stroobants Cardiovascular Center at Lynchburg General.
- The service can be accommodated without adding any staff. Instead, the applicant will re-deploy staff currently employed in cardiac diagnostics services, and cross train them for both SPECT and PET/CT services.
- PET can provide this enhanced image quality in a shorter amount of time than a SPECT. The PET scan test time is 30-40 minutes whereas a SPECT scan is an average of 180 minutes. The shorter PET procedure time will allow for an increase in the number of patients who can be scheduled per day. This is critically important as it will help address the current wait time and backlog for non-emergent SPECT. Because of the length of time associated with a SPECT procedure and the age of Lynchburg General's existing SPECT, Lynchburg General has limited SPECT capacity. As a result, non-emergency patients are waiting up to ten weeks for a SPECT.
- PET/CT imaging has become the gold standard for cardiac imaging. In addition to replacing old SPECT technology which produces lower quality images while subjecting patients to higher radiation levels and long procedure times, PET/CT has become the preferred diagnostic tool for patients presenting to the emergency department with chest pain or other symptoms indicating a potential cardiac event. The enhanced sensitivity and specificity of



PET/CT images results in both (i) fewer false positives and therefore fewer unnecessary cardiac catheterizations, and (ii) fewer false negatives and therefore cases of untreated cardiovascular disease. By adding a cardiac PET/CT scanner to the Stroobants Cardiovascular Center, Centra will be able to provide the advantages of this diagnostic imaging modality to its community and patients.

- The new unit will be a Siemens Biograph mCT Flow edge unit. The Biograph unit was among the world’s first PET/CT systems to eliminate the demand for stop-and-go imaging, with planning and scanning based on a single continuous motion of the patient table. With a single noninvasive procedure, the Biograph produces remarkable PET/CT images that reveal highly detailed anatomy and biological processes at the molecular level.
- Without this project, patients at Centra will continue to face the choice of being referred outside the system for cardiac PET/CT, which disrupts continuity of care and is highly inconvenient, or obtaining alternative cardiac imaging services at Centra.

**(v) the financial accessibility of the proposed project to the people in the area to be the financial accessibility of the proposed project to the people in the area to be served, including indigent people; and**

The Pro Forma Income Statement provided by the applicant includes the provision of charity care in the amount of 0.5% (**Table 5**). As previously discussed, recent changes to § 32.1-102.4B of the Code of Virginia now require DCOPN to place a charity care condition on every applicant seeking a COPN. DCOPN notes that, if approved, the proposed project should be subject to a charity care condition no less than the 0.6% HPR III average, in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

**Table 5. Centra Pro Forma Income Statement**

	<b>Year 1</b>	<b>Year 2</b>
<b>Total Gross Revenue</b>	<b>\$24,115,860</b>	<b>\$25,198,373</b>
Contractual Adjustments	(\$16,519,759)	(\$17,324,758)
Charity Care	(\$122,991)	(\$128,512)
Bad Debt	(\$1,278,141)	(\$1,335,514)
<b>Net Revenue</b>	<b>\$6,194,970</b>	<b>\$6,409,589</b>
Total Operating Expenses	\$1,758,324	\$1,991,288
<b>Operating Income</b>	<b>\$4,436,646</b>	<b>\$4,418,300</b>

Source: COPN Request No. VA-8766

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

On July 20, 2021, the Commissioner denied another request, COPN Request No. VA-8541, to add one cardiac PET/CT unit at Lynchburg General. The Commissioner’s reasons for denial were:

1. The Centra project is not consistent with the SMFP, and is not in harmony or in general agreement with the SMFP or with the planning principles, public policies, interests and purposes to which the SMFP and the COPN law are dedicated;
2. Repurposing or redeployment of an existing health care resource in PD 11, i.e., the PET/CT scanner currently at or proximate to CLGH, to perform imaging in support of oncological care, cardiac care and emergency services is available, and constitutes a viable, more reasonable alternative to the Centra project; and
3. Notwithstanding a numerically derived prima facie need for additional CT capacity at CLGH, the Centra project would unnecessarily duplicate the existing PET/CT scanner, which is underutilized and located at or proximate to CLGH.

With regard to the previous denial and the current application, the applicant explains:

This utilization data supports DCOPN historic findings that “few PET services in the state actually meet the SMFP’s utilization thresholds of 6,000 procedures per existing and approved fixed site PET scanner and [DCOPN] believes that the threshold reflects a misconception about the utilization PET/CT technology at the time that the SMFP PET/CT criteria and standards were written.”

Because none of the existing PET/CTs in the Commonwealth meet this standard, DCOPN and the Commissioner have had to disregard it when reviewing project or else no new PET/CTs could ever be approved. In fact, in the past five (5) years, and as presented in the following table, DCOPN and the State Health Commissioner have approved all PET/CT COPN applications which were accepted for review, with the exception of one, despite this standard never having ever been met...

Notably, despite being the sole health system serving Planning Districts 11 and 14, Centra finds itself in the unique and unfortunate position of being the only applicant denied access to this critical diagnostic technology in the past five (5) years. This denial, in turn, has inadvertently impacted the entire community Centra serves, leaving them without access to this essential service and forcing them to choose between waiting for long periods to receive a SPECT or traveling outside of the Planning District for care.

Given the peak range of about 2,300 PET/CT procedures per scanner identified above, Centra clearly meets an institution-specific need to add capacity because the combined current oncologic PET/CT volume of nearly 1,500 procedures and the projected cardiac PET/CT volume of nearly 1,600 procedures will greatly exceed the threshold of 2,300 procedures. In fact, were Centra able to provide all procedures on the same scanner (which it cannot), that unit would operate at more than 130% of the operational peak range computed above.

In light of the approvals of cardiac PET/CT in numerous physician offices and the presence of multiple PET/CTs within the same planning district, it is both logical and fair that Centra should also receive approval, as it seeks to implement the only cardiac

PET/CT in PD 11 to service not only the Stroobants Cardiovascular Center, but also Lynchburg General's emergency department as a whole. This will not only align with the existing trend and standard of care, but also significantly enhance the quality of healthcare services Centra provides to the community.

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 to determining a public need for the proposed projects.

**3. The extent to which the proposed project is consistent with the State Health Services 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 SMFP.

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

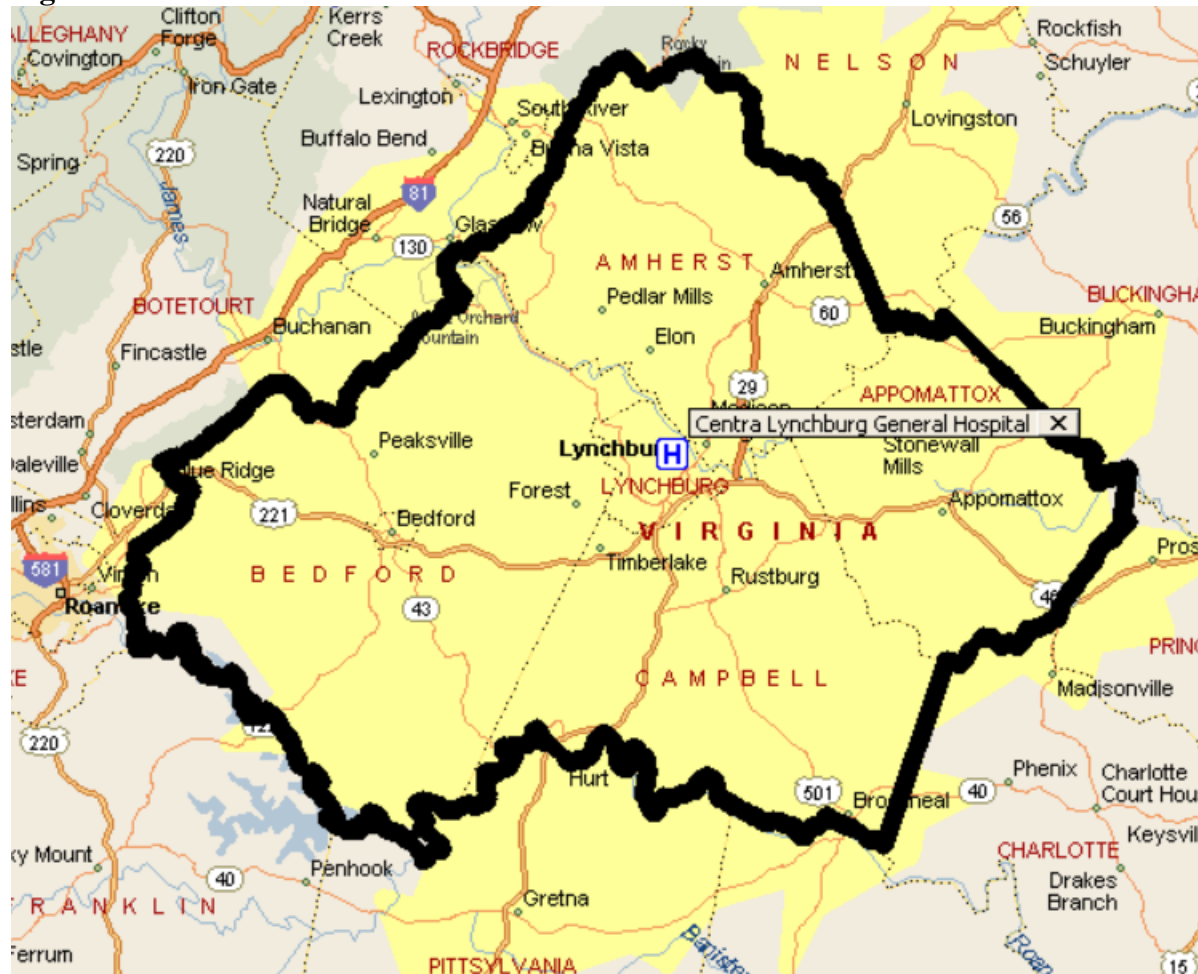
**Part II**  
**Diagnostic Imaging Services**  
**Article 4 Criteria and Standards for Positron Emission Tomography**

**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.**

The heavy black line in **Figure 1** is the boundary of PD 11. The white "H" symbol marks the location of the proposed project. As previously discussed, Lynchburg General is the only provider of PET/CT services in PD 11, and there are no providers of cardiac PET/CT. The yellow shaded area includes the area that is within 60 minutes driving time one-way under normal conditions of existing PET/CT services in PD 11. **Figure 1** clearly illustrates that PET services are already well within a 60-minute drive under normal conditions of 95% of the residents of PD 11 and approval of the proposed project will not increase geographic access to PET services.

Figure 1



**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 1**

**individual PET procedure and CT procedure respectively, unless those images are made concurrently.**

Calculated Needed Fixed PET Scanners in PD 11

Centra Health is the only provider of PET/CT services in PD 11 with one PET/CT unit at Centra Alan B. Pearson Regional Cancer Center (Cancer Center). The unit at the Cancer Center is entirely dedicated to oncological imaging and performed 1,124 scans in 2022 according to VHI data.

Calculated Needed Fixed PET/CT scanners =  $1,124$  (2022 fixed PET procedures)  $\div$   $6,000$  =  $0.19$   
(1) scanners needed

PD 11 Calculated Need = 1 PET/CT scanners

2024 PET/CT Scanners = 1 PET/CT scanners

There is neither a surplus nor a deficit of PET/CT scanners in PD 11.

**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.**

The SMFP does not distinguish between cardiac PET and PET used for other clinical uses. As shown above, there is neither a surplus nor a deficit of PET/CT scanners in PD 11. DCOPN notes, according to VHI data for 2022, the average number of PET procedures performed across all PET providers in the entire Commonwealth was 1,163, with a low of two procedures at Parham Doctors' Hospital and a high of 5,882 at Carilion Roanoke Memorial Hospital. No provider in the Commonwealth surpassed the 6,000-procedure threshold in 2022.

DCOPN has previously acknowledged the SMFP's utilization standards for PET/CT services are outdated and that expecting a PET service to reach the threshold suggested by the SMFP amounts to a misconception about the utilization of this modality at the time the SMFP was written, and should be treated as such:

Consistency with SMFP planning guidance in this case is, in effect, an academic exercise. The assumptions underlying the service volume standards, for example, have been superseded by technological developments (e.g., shorter average scan times) and the failure to identify additional clinical applications for the technology. Moreover, none of the existing services met fully the SMFP review criteria and standards when they obtained COPN authorization. (Source: Health Systems Agency of Northern Virginia Staff Report RE: COPN Request No. VA-8327, November 28, 2017).

More recently, in its November 29, 2022 report for COPN Request No. VA-8626, the HSANV observed “[i]t is evident that there is a wholesale shift underway from SPECT to PET-CT imaging as the preferred imaging modality in cardiovascular care...” and “[c]ardiac PET imaging in Northern Virginia has developed separately from other PET imaging services. This

may not be desirable but is an operational reality that must be acknowledged....” and “[u]ntil recently Northern Virginia PET services have been organized, structured and equipped to serve oncology patients. Few cardiac patients are referred for PET scans. Metro Region PET, the region’s largest PET service, reports less than a dozen cardiac patient scans (less than 0.5% of Metro PET’s caseload) in recent years. None of the older services offer the PET based myocardial perfusion imaging....”

The applicant anticipates performing 1,530 PET/CT studies in Year 1 and 1,567 PET/CT studies in Year 2. To determine these projections, the applicant examined its historical cardiac diagnostic imaging modalities utilization and market growth. Specifically, Lynchburg General is projecting that 35% of its 940 inpatient and emergency department SPECTs, stress echocardiograms as well as exercise treadmill tests will convert to cardiac PET/CT. In addition, Lynchburg General is projection that 77% of its 1,208 existing outpatient SPECT cases will convert to cardiac PET/CT once it is available. Furthermore, in addition to performing cardiac PET/CT studies, the new PET/CT scanner will also allow for myocardial viability studies and detection of sarcoidosis, which the applicant projects to be 125 studies.

With regard to the effect that the proposed project would have on existing providers, there are no providers of cardiac PET/CT in PD 11 and Lynchburg General is the only provider of PET/CT services in the planning district.

While the applicant does not meet the computational analysis of this SMFP standard, DCOPN recommends that the Commissioner, in this specific instance, does not allow this standard to bar the establishment of this cardiac PET/CT service.

**12VAC5-230-230. Adding or Expanding 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. The applicant is not proposing to add or expand an existing mobile PET/CT service, but rather, is proposing to add a new fixed-site service.

**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 provided assurances that PET services will be under the direction and supervision of one or more qualified physicians who are appropriately authorized and licensed to interpret cardiac PET/CT studies.

**Eight Required Considerations Continued**

- 4. The extent to which the proposed project fosters institutional competition that benefits the area to be served while improving access to essential health care services for all people in the area to be served;**

Centra is the only provider of PET/CT services in PD 11. Therefore, it is unlikely that the proposed project will foster institutional competition.

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

Centra is the only provider of inpatient care services in PD 11. Therefore, DCOPN concludes that the proposed project will not adversely affect the utilization and efficiency of existing services or facilities.

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

As already discussed, DCOPN contends that the projected costs for the proposed project of \$4,076,814 are reasonable when compared to similar projects. For example, COPN No. VA-04874 issued to University of Virginia Medical Center to establish a specialized center for PET with one PET/CT unit is anticipated to cost approximately \$4,000,000.

The Pro Forma Income Statement provided by the applicant anticipates a net profit of \$4,436,646 in the first year of operation and \$4,418,300 by year two, illustrating that the proposed project is financially feasible both in the immediate and the long-term. (**Table 5**).

With regard to staffing, the applicant does not anticipate the need to hire any additional staff. Rather, it will re-deploy staff currently employed in cardiac diagnostic services, and cross train them for both SPECT and PET/CT services.

- 7. The extent to which the proposed project provides improvements or innovations in the financing and delivery of health care 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 health care services on an outpatient basis; (iii) any cooperative efforts to meet regional health care needs; and (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 providing access to the latest, most accurate technology on an outpatient basis. Additionally, as there are no existing providers of cardiac PET/CT scanning services in PD 11, the proposed project would 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. DCOPN did not identify any other factors as may be appropriate to bring to the Commissioner's attention.

DCOPN did not identify any other factors as may be appropriate to bring to the Commissioner's attention.

- 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 and (ii) any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care services for citizens of the Commonwealth, including indigent or underserved populations.**

The applicant is not a teaching hospital or affiliated with a public institution of higher education or medical school in the area to be served. The proposed project would not contribute to the unique research, training, or clinical mission of a teaching hospital or medical school.

### **DCOPN Staff Findings and Conclusions**

DCOPN finds that Centra Health, Inc.'s proposed project to add a PET/CT unit for cardiac imaging at Lynchburg General is generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. The applicant has stated that the CT functionality of the PET/CT scanner will be used only in conjunction with its PET functionality and that the PET/CT scanner would be used solely for cardiac imaging. While the planning district does not meet the utilization threshold for the establishment of a new service, DCOPN notes that precedent has been established by the Commissioner regarding this threshold not barring the establishment of new PET/CT services when sufficiently compelling circumstances exist. As such compelling reasons exist, such as the clinical advantages of PET/CT over SPECT, DCOPN recommends that the Commissioner, in this specific instance, not allow this standard to bar the establishment of cardiac PET/CT services at this location.



Additionally, DCOPN finds that the proposed project is more beneficial than the alternative of the status quo. Furthermore, DCOPN finds that the total capital costs of the proposed project compare favorably to similar, recently approved projects.

### **DCOPN Staff Recommendation**

The Division of Certificate of Public Need recommends **conditional approval** of Centra Health, Inc.'s COPN Request No. VA-8766 to add a PET/CT unit for cardiac imaging at Lynchburg General for the following reasons:

1. The project is generally consistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.
2. The PET/CT scanner's use will be limited solely to cardiac imaging.
3. The CT functionality of the PET/CT scanner will only be utilized in conjunction with the PET functionality.
4. The project will improve access to the preferred cardiac imaging modality with numerous benefits over SPECT.
5. The project is more beneficial than the alternative of the status quo.
6. The capital costs are reasonable.

DCOPN's recommendation is contingent upon Centra Health, Inc.'s agreement to the following charity care condition:

### **Recommended Condition**

Centra Health Inc. will provide PET/CT services to all persons in need of these services, 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 0.6% of Centra Health, Inc.'s total patient services revenue derived from PET/CT 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 Centra Health, 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.

Centra Health, Inc. will provide PET/CT care 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 Centra Health, 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.