

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis Report

March 22, 2021

COPN Request No. VA-8541

Centra Health, Inc.

Lynchburg, Virginia

Add one PET/CT scanner for the provision of cardiac imaging at Centra Lynchburg General Hospital

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 (“CLGH”). CLGH is located in the city of Lynchburg, Health Planning Region (HPR) III, Planning District (PD) 11.

Background

CLGH has been in operation since 1956 at its present location. Until 1987, when the hospital merged with Virginia Baptist Hospital, also located in Lynchburg, to form Centra Health, Inc., the facility operated as Lynchburg General Hospital, Inc., an independent community based 501(c)(3) not-for-profit non-stock corporation. CLGH is 358-bed full service hospital that provides a variety of services including oncology, cardiovascular services, emergency services, laboratory services, physical therapy services, and diagnostic imaging. On August 15, 2016, the Virginia State Health Commissioner (“Commissioner”) issued COPN No. VA-04520 authorizing Centra Health Inc. to introduce fixed positron emission tomography/computed tomography (PET/CT) services at CLGH through the installation of a stationary PET/CT Scanner at the CLGH Alan B. Peterson Regional Cancer Center and the discontinuation of mobile PET/CT services at the location. In 2018, the last year for which DCOPN has data available from Virginia Health Information (“VHI”), CLGH’s one PET/CT scanner, that represents the totality of PET/CT services in PD 11, operated at 14.5% of the State Medical Facilities Plan (“SMFP”) utilization threshold. During the same period, the 8 COPN authorized CT scanners in PD 11 operated at 101.4% of the SMFP threshold. DCOPN records show that there are currently 9 COPN authorized CT scanners in PD 11, and that the sole COPN authorized PET scanner in PD 11 is located at CLGH.

Table 1. Fixed PET/CT Services and 2018 Utilization in PD 11

Fixed PET Services	Units	Procedures	Procedures/Unit	Utilization Rate
Lynchburg General Hospital	1	871	871	14.5%
2018 Fixed PET Total and Average	1	871	871	14.5%
2020 Fixed PET Total	1	N/A	N/A	N/A

Table 2. Fixed CT Services and 2018 Utilization in PD 11

Fixed PET Services	Number of Scanners	Number of Scans	Utilization Rate
Bedford Memorial Hospital	1	6,542	88.4%
Blue Ridge Ear, Nose, Throat and Plastic Surgery	1	640	8.6%
Central Virginia Imaging	1	10,469	141.5%
Lynchburg General Hospital	4	38,817	131.1%
Virginia Baptist Hospital	1	3,537	47.8%
2018 Fixed CT Unit Total and Average	8	60,005	101.4%
2020 Fixed CT Unit Total	9	N/A	N/A

Proposed Projects

The applicant proposes to add one PET/CT scanner at CLGH. The proposed scanner would be located inside CLGH at the Stroobants Cardiovascular Center. The proposed project would increase the number of PET/CT scanners located at CLGH to two. The applicant plans to use the CT functionality of the proposed PET/CT scanner, both in conjunction with the PET functionality, and independent of PET functionality. The applicant has proffered that the PET/CT scanner’s use will be limited to solely cardiovascular indications. The applicant asserted in their application that the existing PET/CT scanner is currently fully utilized and would not be able to accommodate any of the cardiac PET/CT scans at CLGH. DCOPN reached out to the applicant to reconcile this assertion with the 2018 VHI utilization data for the PET scanner. The applicant subsequently amended their assertion to indicate that the current PET scanner had additional capacity, but maintained that the current scanner could not be utilized for cardiac indications for other factors discussed in detail below. The applicant additionally states that currently patients must travel at least an hour to either Roanoke, Charlottesville, or Durham, North Carolina to receive cardiac PET/CT services. The total capital and financing cost of the proposed project is \$3,083,178 (**Table 3**). The project would be paid for by the use of CLGH’s accumulated reserves. The applicant asserts that it does not anticipated that the proposed project will affect the cost of its services.

Table 3. Capital and Financing Costs

Direct Construction Costs	\$892,584
Equipment Not Included in Construction Contract	\$2,037,336
Site Preparation Costs	\$15,000
Architectural and Engineering Fees	\$88,258
Other Consultant Fees	\$50,000
TOTAL Capital and Financing Costs	\$3,083,178

Source: COPN Request No. VA-8541

Project Definition

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... computed tomographic (CT) scanning [and]... 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 exists for a proposed project, the following factors shall be taken into account when applicable:

- 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;**

The applicant proposes to add one PET/CT scanner to be located in the Stroobants Cardiovascular Center. The applicant asserts that the proposed project would represent the first PET/CT scanner that would perform cardiac scans within PD 11 and that approval of the project is necessary to avoid the drive of over an hour currently experienced by patients in PD 11 seeking cardiac PET services. The applicant additionally asserts that the existing PET/CT scanner, while having capacity, is not a viable option. The applicant’s first reason is that the Cancer Center is not equipped or staffed to do cardiac PET scanning. This is not surprising, as they do not currently offer cardiac PET scanning at this location, but the applicant does not provide any compelling reason why this location could not be equipped and be staffed, at least part time, to provide cardiac PET scans. Next, the applicant asserts that about half of the patients requiring cardiac PET/CT scans are inpatients that would need to be discharged from the hospital and transported by ambulance the approximately 0.4 miles to the cancer center before being driven back by ambulance to be readmitted. DCOPN finds this ratio of inpatient scans to be extremely dubious. In the entire Commonwealth of Virginia, VHI reported that only 125 inpatient PET procedures were performed across all PET scanners, both fixed and mobile, in 2018. If the applicant’s assertion that the majority of Single Photon Emission Computed Tomography (SPECT) scans at CLGH would instead receive PET scans is to be believed¹, then, using their 2018 SPECT numbers, their estimation would generate inpatient scans equaling approximately 7.6 times the total scans in the Commonwealth during the same period. Additionally, even if these numbers were correct, the same outcome could be reached without compounding the low utilization of PET services at CLGH by moving the extremely underutilized PET/CT scanner from the cancer center to CLGH, where both oncology and cardiovascular scans could be performed without discharging patients. As such, DCOPN concludes that the applicant has not made a case for any benefit of the proposed project that could not be found in a less costly, more efficient, or more effective manner through the use of the ample capacity available in their existing PET scanner.

¹ VHI reports the total number of SPECT scans performed, without differentiating cardiac from brain, or other organ/system. In 2018 VHI reports that CLGH performed 322 inpatient SPECT scans and 1,590 outpatient SPECT scans of all types.

Geographically, the CLGH is accessible via US-29, US-501, and US-460, all of which are accessible within five miles of CLGH. Public transportation is readily available via the Greater Lynchburg Transit Authority via multiple stops per day on the hospital campus. Additionally, Centra's P.A.C.E. program provides non-emergent transportation for program participants to medical appointments, including those at CLGH.

DCOPN is not aware of any other geographic, socioeconomic, cultural, or transportation barriers to access to care.

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 seven letters of support from physicians associated with Centra. Collectively, these letters discussed the benefits of PET/CT over SPECT for cardiac imaging. Moreover, these letters articulated the lack of cardiac PET/CT imaging in PD 11.

Public Hearing

DCOPN provided notice to the public regarding this project on February 2, 2021. The public comment period closed on March 19, 2021. Section 32.1-102.6 of the Virginia Code mandates that "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, [DCOPN shall] hold one hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city." The proposed project is not competing, and no public hearing was requested by the applicant, the Commissioner, an interested party, or member of the public. As such, 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;

As discussed in detail above, all of the benefits of the proposed project can be met in a less costly, more efficient, or more effective manner through the use of the ample capacity available with their existing PET scanner. The applicant asserts that their existing PET scanner performed 992 scans in 2019. During the same period, the applicant reports that their SPECT scanner performed 2,000 scans. The applicant asserts in their application that the PET/CT scan would be significantly quicker than the current SPECTs scans and provides an estimate of 30-40 minutes per scan. Given the speed at which these cardiac PET scans can be performed, it seems highly unlikely that the current PET/CT scanner, with its extremely low utilization, does not have capacity for both oncology and cardiovascular indications. Additionally, even should all SPECT scans be converted to cardiac PET scans, combining these numbers still puts the capacity of the existing PET scanner below 50% of the 6,000 scan threshold mandated by the SPMFP for expansion of PET services in 2019. Moreover, should the staggeringly high numbers of inpatient scans estimated by the

applicant, approximately 7.6 times the total inpatient scans for the entire Commonwealth in 2018, be correct, the current PET/CT scanner could be relocated to the main hospital where it could more effectively be utilized to provide PET services for this unprecedented situation. As all of the benefits of the proposed project can be effectuated without the proposed, DCOPN concludes that maintenance of the status quo or relocation of the CLGH's existing PET to the hospital would meet the needs of the people in the area to be served in a less costly, more efficient, or more effective manner

(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.

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

As discussed above, the total capital and financing cost of the proposed project is \$3,083,178 (**Table 3**) and would be paid for by the use of CLGH's accumulated reserves. The costs for the project are reasonable and generally consistent with previously approved projects to add one fixed PET/CT scanner. For example, COPN VA-04525 issued to Centra Health, Inc. to introduce PET/CT services at Centra Lynchburg General Hospital through the addition of one fixed PET/CT unit at the Alan B. Peterson Regional Cancer Center, which cost approximately \$3,183,137. For cardiac imaging, PET/CT scanners offer several advantages over the SPECT scanners currently being used by CLGH. First, PET/CT offers better resolution scans compared to the SPECT scanners. Secondly, cardiac PET/CT has the unique ability to quantify, non-invasively, myocardial blood flow, which enables cardiologists to obtain a more complete workup of the heart, arteries, and surrounding microvasculature by analyzing flow at rest and during stress². Lastly, the cardiac PET/CT scan can be completed in less time than the cardiac SPECT scan. While DCOPN acknowledges the benefits of PET imaging over SPECT imaging for cardiac patients, the fact remains that the same outcome could be reached without the proposed project by using of the existing highly underutilized PET/CT scanner at CLGH.

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

According to regional and statewide data regularly collected by VHI, for 2018, the average amount of charity care provided by the facilities in HPR III that reported such charity care for that year was 3.1% of all reported total gross patient revenues. As **Table 3** below demonstrates, during the same period, Centra Health, which includes CLGH, provided 3.83% of its gross patient revenue in the form of charity care. In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project be approved, CLGH is expected to

² COPN Request No. VA-8315 DCOPN Staff Report p. 2

provide a level of charity care for total gross patient revenues derived from psychiatric services that is no less than the equivalent average for charity care contributions in HPR III.

Table 3. HPR III 2018 Charity Care Contributions

2018 Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Carilion Franklin Memorial Hospital	\$140,570,971	\$12,554,448	8.93%
Carilion Tazewell Community Hospital	\$56,372,076	\$4,461,261	7.91%
Carilion New River Valley Medical Center	\$641,976,306	\$35,497,216	5.53%
Bedford Memorial Hospital	\$106,076,131	\$5,296,511	4.99%
Carilion Medical Center	\$3,558,873,340	\$159,649,849	4.49%
Wellmont Lonesome Pine Mt. View Hospital	370345839	16158822	4.36%
Dickenson Community Hospital	\$25,823,572	\$1,031,068	3.99%
Russell County Medical Center	\$110,087,349	\$4,369,909	3.97%
Centra Health	\$2,328,985,662	\$89,202,278	3.83%
Carilion Giles Memorial Hospital	\$93,368,852	\$3,016,041	3.23%
Smyth County Community Hospital	\$191,874,758	\$5,908,813	3.08%
Johnston Memorial Hospital	\$849,445,825	\$23,815,840	2.80%
Norton Community Hospital	\$290,440,432	\$7,990,982	2.75%
Lewis-Gale Medical Center	\$2,081,736,631	\$45,082,951	2.17%
Pulaski Community Hospital	\$306,530,249	\$6,493,909	2.12%
LewisGale Hospital -- Montgomery	\$578,517,580	\$9,337,489	1.61%
LewisGale Hospital -- Alleghany	\$196,433,577	\$2,962,798	1.51%
Twin County Regional Hospital	\$235,254,272	\$2,331,223	0.99%
Clinch Valley Medical Center	\$492,663,256	\$4,385,186	0.89%
Buchanan General Hospital	\$98,290,606	\$540,974	0.55%
Memorial Hospital of Martinsville & Henry County	\$680,100,049	\$2,249,897	0.33%
Wythe County Community Hospital	\$224,998,295	\$633,916	0.28%
Danville Regional Medical Center	\$866,889,606	\$377,575	0.04%
Total \$ & Mean %	\$14,525,655,234	\$443,348,956	3.1%

Source: VHI

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

Section 32.1-102.2:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop, by November 1, 2022, 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).

3. The extent to which the proposed project is consistent with the State Health Services Plan;

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

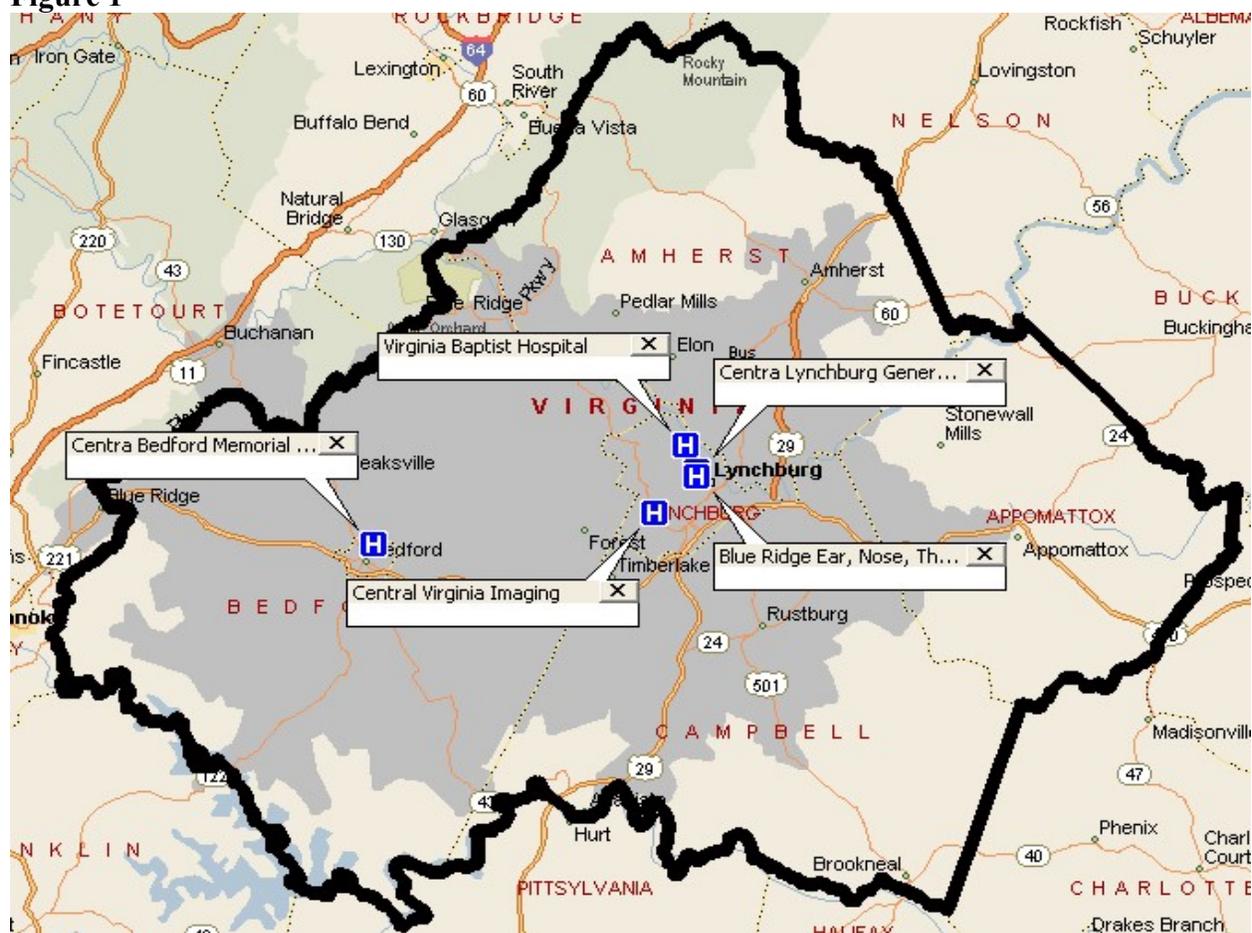
Part II
Diagnostic Imaging Services
Article 1
Criteria and Standards for Computed Tomography

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.

Currently, there are 9 COPN authorized CT scanners in PD 11. The heavy black line in **Figure 1** is the boundary of PD 11. The blue H icons indicate facilities that currently offer fixed CT services. The grey shading illustrates the area that is within a thirty-minute drive under normal driving conditions of all CT service providers in PD 11. Based on the shading in **Figure 1**, DCOPN concludes that CT services may not currently be within thirty minutes of 95% of the population of PD 11. However, as the proposed project would be located in a facility that already provides CT services, the proposed project would not increase access to patients not currently within a thirty-minute drive under normal driving conditions of CT services.

Figure 1



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.

Calculated Needed Fixed CT Scanners in PD 11

COPN authorized CT scanners = 9

Calculated Needed CT scanners =

$60,005 \text{ scans}^3 \text{ in the PD} / 7,400 \text{ scans} / \text{scanner} = 8.1 \text{ (9) scanners needed}$

PD 11 Calculated Need = 9 CT scanners

PD 11 Calculated Surplus/Deficit = 0 CT scanners

As noted in **Table 2** above, the utilization of existing CT scanners in the planning district in 2018, the last year for which DCOPN has data from VHI, was 101.4% of the 7,400 procedures per scanner necessary to introduce CT scanning services to a new location under this section of the SMFP. In March 2020 Central Virginia Imaging opened a second CT scanner (COPN No. VA-04666) bringing the PD 11 inventory to nine diagnostic CT scanners. DCOPN calculates that there is currently neither a surplus nor a deficit of fixed CT scanner in PD 11. As CLGH is an existing provider of CT services, this section seeks merely to provide an overview of fixed CT scanners within PD 11.

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 the existing CT scanner used solely for simulation prior to the initiation of radiation therapy at Lynchburg General Hospital from the inventory and average utilization of CT scanners in PD 11 with respect to the proposed project.

³ As noted in **Table 2** above, the 60,005 scans in 2018 were performed on 8 scanners.

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.

The applicant asserts this section is not applicable to the proposed project and that, in past PET/CT reviews, DCOPN has not separately performed a review of the CT portion of the SMFP during a review of a PET/CT project. DCOPN assumes that the applicant is referencing past PET/CT scanner reviews in which the applicant proffered that the CT functionality of the PET/CT scanner would only be used in conjunction with the PET functionality. In cases where the CT functionality would also be used without the PET functionality, DCOPN has consistently performed a separate CT analysis. As such, DCOPN contends that this analysis is both appropriate and necessary for the proposed project.

In 2018, the last year for which DCOPN has data available from VHI, CLGH operated at 131.1% of the SMFP threshold. Moreover, CLGH has proffered that any use of the CT functionality not in conjunction with the PET functionality will be limited to existing CLGH patients with cardiovascular indications. As such, DCOPN concludes that the use of the CT portion of the PET/CT independently will not reduce the utilization of existing providers and that the applicant has met the volume threshold.

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.**

Not applicable. The applicant is not proposing 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.

The applicant stated that the proposed PET/CT scanner would be under the direction and supervision of qualified physicians who are appropriately authorized and licensed to interpret cardiac PET/CT studies.

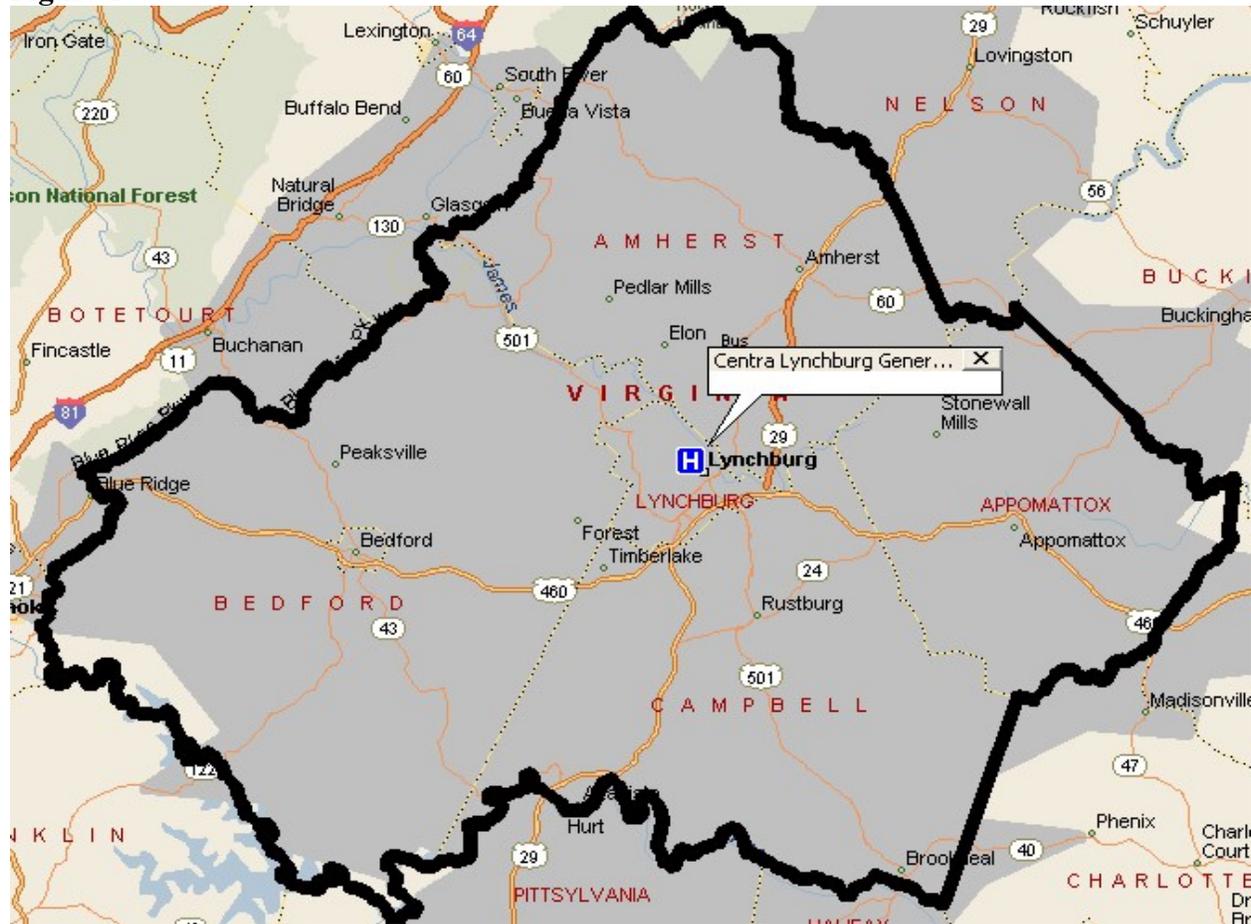
Part II
Diagnostic Imaging Services
Article 4
Criteria and Standards for Positron Emission Tomography

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.

Currently, there is one COPN authorized PET scanner in PD 11. The heavy black line in **Figure 1** is the boundary of PD 11. The blue H icons indicate facilities that currently offer fixed PET services. The grey shading illustrates the area that is within a sixty-minute drive under normal driving conditions of all PET service providers in PD 11. As the proposed PET scanner would be located at the sole facility providing PET services in PD 11, DCOPN concludes that the proposed project would not increase access to patients not currently within a sixty-minute drive under normal driving conditions of PET services. However, as **Figure 1** clearly illustrates, PET services are already within a sixty-minute drive under normal conditions of 95% of the residents of the planning district.

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.

Not applicable. The applicant is seeking to expand an existing fixed site service and not proposing to establish a new fixed site service.

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 applicant states that that CLGH has an institutional need and community need to expand its fixed PET services. With regard to the assertion of institutional need, as discussed above, subsequent correspondence from the applicant showed CLGH actually had additional capacity and no institutional need existed. Additionally, as the purpose of DCOPN's report is to gauge community need, the simple assertion by the applicant that community need exists cannot be so simply adopted by DCOPN, nor should it be used as a reason to set aside one of the criteria used to test this need. Finally, the applicant states that this standard is not applicable. As this is the standard for evaluating the need to expand fixed PET services, which the applicant is seeking with this application, DCOPN rejects this assertion.

As noted in **Table 1** above, the one fixed site PET scanners in PD 1 performed total of 871 procedures in 2018, with a utilization of 14.5% of the SMFP threshold of 6,000 procedures per scanner per year. The applicant cites DCOPN's staff report for COPN Request No. VA-8449 stating:

“DCOPN notes 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 believes that the threshold reflects a misconception about the utilization of PET/CT technology at the time that the SMFP PET/CT criteria and standards were written.”

However, this statement is addressing 12VAC5-230-210, which addresses the establishment of a new service, rather than the current section, which addresses the expansion of fixed site services. This is an important distinction as the intent of this statement in 12VAC5-230-210 was to not let a difficult to reach threshold permanently prevent new providers from entering the market. This intent is clearly not applicable to the current section as one could hardly reasonably assume that DCOPN was recommending no threshold be applied to the expansion of existing services when the gauging of the effective utilization of these services is the sole point of this threshold. Currently, there is only one facility with more than one fixed PET scanner in the Commonwealth, Carilion Roanoke Memorial Hospital. The second PET scanner at Carilion Roanoke Memorial Hospital was authorized by the Commissioner⁴ because Carilion Roanoke Memorial Hospital demonstrated an institutional need to expand. In its report, DCOPN determined that the Carilion Roanoke Memorial Hospital's one fixed PET/CT scanner had a utilization of 104.2% of the SMFP threshold of 6,000 procedures per scanner per year.

⁴ COPN No. VA- 04646

For the reasons discussed above, DCOPN rejects the assertions by the applicant that section 12VAC5-230-220 of the SMFP is not applicable to the proposed project, and that the 6,000 procedure standard should be set aside in cases where an existing provider is seeking to expand their PET service. Based on the utilization data provided by VHI and the applicant, DCOPN concludes that the applicant does not meet this standard.

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 mobile PET or PET/CT services or to convert authorized mobile PET or PET/CT scanners to fixed site scanners.

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 stated that the proposed PET/CT scanner would be under the direction and supervision of qualified physicians who are appropriately authorized and licensed to interpret cardiac PET/CT studies. The applicant additionally listed the names and credentials of 12 physicians at CLGH that would provide direction and supervision.

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;**

With regards to the PET portion of the project, as Centra is the sole provider of PET services in PD 11, DCOPN concludes that the approval of the PET portion of the proposed project will not foster institutional competition. With regards to the CT portion of the proposed project, CLGH is an existing provider of CT services whose 4 scanners exceeded the SMFP threshold in 2018 by a significant amount. Approval of the CT portion of the proposed project would increase the number of CT scanners in the planning district to 10, with 5 located at CLGH. Given CLGH's dominance in the marketplace, further expansion of their CT services is highly unlikely to foster, and may even reduce, institutional competition that would benefit the area to be served.

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;

As discussed above, DCOPN determined that the benefits of the proposed project could be met more efficiently through the use of its existing highly underutilized PET/CT scanner. Moreover, DCOPN contends that the proposed project would exacerbate this underutilization by introducing another PET/CT scanner whose PET functionality would also operate far below the SMFP threshold.

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;

The total capital and financing cost of the proposed project is \$3,083,178 (**Table 3**) and are reasonable and generally consistent with previously approved projects to add one fixed PET/CT scanner. For example, COPN VA-04525 issued to Centra Health, Inc. to introduce PET/CT services at Centra Lynchburg General Hospital through the addition of one fixed PET/CT unit at the Alan B. Peterson Regional Cancer Center, which cost approximately \$3,183,137. As discussed above, the proposed project would be funded entirely through the use of CLGH's accumulated reserves. As such, DCOPN concludes that the proposed project is feasible with regard to financial costs.

With regard to staffing, the applicant asserts that the proposed project will be effectuated using solely the existing SPECT technicians. To the extent to which additional training will be required, the applicant asserts that they will provide this training to their employees. As there are no additional staffing needs, DCOPN concludes that the proposed project is feasible with regards to staffing.

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; and

As discussed above, while there are benefits to the applicant beginning to perform PET scans on cardiac patients, this can be better effectuated through the efficient use of the applicant's existing highly underutilized PET/CT scanner.

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.

The applicant provided the following with regard to this standard:

“Centra has a long tradition of learning and teaching, beginning with the School of Nursing in 1912 and continuing with Lynchburg Family Medicine Residency in 1975. Every year Centra healthcare professionals and members of Central Virginia’s extended medical community help mentor and train hundreds of medical learners and allied health professionals. As the medical industry expands, area schools look Centra to provide quality medical learning experiences for the next generation health care professionals. Unlike a traditional teaching hospital, Centra offers an innovative approach to medical and allied healthcare education, building precepting models geared towards interprofessional teams in acute and primary care settings.

Centra’s Office of Medical Education and Student Affairs (“OMESA”) acts as an administrative center for student relations and onboarding within Centra. The OMESA team works on behalf of multiple academic partners to place medical learners within Centra’s teaching practices and throughout the extended medical community. OMESA partners closely with the Liberty University College of Osteopathic Medicine and the University of Lynchburg Master of Physician Assistant Medicine programs as well as other local academic programs in an effort to ‘educate the next generation of healthcare professionals in our community, for our community.’

The addition of a cardiac PET/CT service at [CLGH] will provide medical and allied healthcare students with the opportunity to learn about advanced imaging techniques in the diagnosis and treatment of cardiovascular disease.”

DCOPN Staff Findings and Conclusion

DCOPN finds that the proposed project to add one fixed PET/CT scanner at CLGH is not consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. While the applicant established a need to expand its CT services, ample unused capacity exists with the applicant’s existing PET scanner. While the applicant argues that the threshold set by 12VAC5-230-220 should be ignored and cites DCOPN precedent, this precedent, as well as the logic behind it, is applicable solely towards establishing a new PET service and has never been used by DCOPN to authorize the expansion of PET services.

Moreover, DCOPN finds that maintenance of the status quo or relocation of the CLGH’s existing PET to the hospital would meet the needs of the people in the area to be served in a less costly, more efficient, or more effective manner. While the applicant makes several arguments as to why this is not the case, DCOPN has explained in detail throughout its report why none of these objections are particularly solid or compelling. Finally, DCOPN finds that the total capital costs of the proposed project are \$3,083,178 (**Table 3**), which would be paid through the use of

CLGH's accumulated reserves. The costs for the project are reasonable and generally consistent with previously approved projects to add one fixed PET/CT scanner. For example, COPN VA-04525 issued to Centra Health, Inc. to introduce PET/CT services at Centra Lynchburg General Hospital through the addition of one fixed PET/CT unit at the Alan B. Peterson Regional Cancer Center, which cost approximately \$3,183,137.

Staff Recommendation

The Division of Certificate of Public Need recommends **denial** of the Centra Lynchburg General Hospital's COPN request number VA-8541 to add one fixed PET/CT scanner for the following reasons:

1. The project is not consistent with the applicable criteria and standards of the State Medical Facilities Plan and the Eight Required Considerations of the Code of Virginia.
2. While the applicant has established a need for CT services, ample unused capacity exists with the applicant's existing PET scanner.
3. Maintenance of the status quo or relocation of the CLGH's existing PET from the cancer center to the hospital would meet the needs of the people in the area to be served in a less costly, more efficient, or more effective manner.