



COMMONWEALTH of VIRGINIA

Karen Shelton, MD
State Health Commissioner

Department of Health
P O BOX 2448
RICHMOND, VA 23218

TTY 7-1-1 OR
1-800-828-1120

August 20, 2025

Thomas J. Stallings
McGuireWoods
Gateway Plaza
800 East Canal Street
Richmond, Virginia 23219-3916

RE: **COPN No. VA-04955 (COPN Request No. VA-8823)**
Lewis-Gale Medical Center, LLC
Roanoke, Virginia
Establish a Center for CT Imaging with 1 CT Scanner

Dear Mr. Stallings:

In accordance with Chapter 4, Article 1.1 of Title 32.1 of the Code of Virginia of 1950 (the Code), as amended, I reviewed the application and all supporting documents submitted by Lewis-Gale Medical Center, LLC to Establish a Center for CT Imaging with 1 CT Scanner in Roanoke, Virginia.

As required by Section 32.1-102.3B of the Code, I have considered all factors that must be taken into account in a determination of public need, and I have concluded that **conditional approval** of the request is warranted based on the following findings:

1. The proposed 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. Approval of the proposed project is not likely to have a significant negative impact on the utilization, costs or staffing of other area providers of CT services.
3. The proposed project is financially feasible in the immediate and the long-term.
4. There is no opposition to the proposed project.

This certificate is valid for the period August 20, 2025 through August 19, 2026. The total authorized capital and financing cost of the project is \$1,002,090 with an expected competition date of June 30, 2028.

Thomas J. Stallings
Lewis-Gale Medical Center, LLC
August 20, 2025
Page 2

Please file two copies of the application for a certificate extension with the Department no later than 30 days before the expiration date of the certificate. Part VIII of the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations identifies the filing requirements and review procedure for certificate extension requests.

Sincerely,



Karen Shelton, MD
State Health Commissioner

Enclosure

cc: Charis A. Mitchell, Assistant Attorney General, Commonwealth of Virginia
Erik Bodin, Director, Division of Certificate of Public Need
James Jenkins, Acting Director, VDH, Office of Licensure and Certification
Deborah K. Waite, Chief Operating Officer, Virginia Health Information
Cynthia Morrow, MD, MPH, District Director, Roanoke City Health District

COMMONWEALTH OF VIRGINIA
DEPARTMENT OF HEALTH

MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED

THIS CERTIFICATE THAT Lewis-Gale Medical Center, LLC. is authorized to initiate the proposal as described below.

NAME OF FACILITY: Hollins ER

LOCATION: 645 & 7655 Williamson Road, Roanoke, Virginia

OWNERSHIP AND CONTROL: Lewis-Gale Medical Center, LLC.

SCOPE OF PROJECT: Establish a specialized center for computed tomography (CT) imaging with one CT scanner. Capital costs authorized for this project total \$1,002,090. The project is expected to be completed with approval of the certificate of public need, about June 30, 2028. This certificate is issued with the condition that appears on its reverse.



Pursuant to Chapter 4, Article 1:1 of Title 32.1, Sections 32.1-102.1 through 32.1-102.12 of the Code of Virginia (1950), as amended and the policies and procedures promulgated thereunder, this Medical Care Facilities Certificate of Public Need is issued contingent upon substantial and continuing progress towards implementation of the proposal within twelve (12) months from the date of issuance. A progress report shall be submitted to the State Health Commissioner within twelve (12) months from the date of issuance along with adequate assurance of completion within a reasonable time period. The Commissioner reserves the right not to renew this Certificate in the event the applicant fails to fulfill these conditions. This Certificate is non-transferable and is limited to the location, ownership, control and scope of the project shown herein.

Certificate Number: VA-04955

Date of Issuance: August 20, 2025

Expiration Date: August 19, 2026

Quinton W.D.

Karen Shelton, MD, State Health Commissioner

Lewis-Gale Medical Center, LLC will provide CT imaging services at Hollins ER 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 will facilitate the development and operation of primary medical care services to medically underserved persons in PD 5 in an aggregate amount equal to at least 0.5% of Lewis-Gale Medical Center's Hollins ER gross patient revenue derived from CT imaging services. 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. Lewis-Gale Medical Center, LLC 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 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.

Lewis-Gale Medical Center, LLC will provide CT imaging services to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1395 et seq.), and 10 U.S.C. § 1071 et seq. Additionally, Lewis-Gale Medical Center, 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.

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-8823
Lewis-Gale Medical Center, LLC
Salem, Virginia
Establish a Specialized Center for CT Imaging with One CT Scanner

Applicant

Lewis-Gale Medical Center, LLC (Lewis-Gale) is Delaware Limited Liability Company established in 1998 whose sole member is Lewis-Gale Hospital, Inc. Lewis-Gale is a 506-bed general hospital located in Health Planning Region (HPR) III, Planning District (PD) 5. Lewis-Gale is a subsidiary of HCA Healthcare, Inc., a for-profit operator of healthcare facilities founded in 1968 and based in Nashville, Tennessee.

Background--Computed Tomography (CT) Scanners and Utilization in PD 5

A computed tomography (CT) scan is a diagnostic imaging tool that utilizes x-ray technology to produce imaging of the inside of the body and can show bones, muscles, organs, and blood vessels. CT scans are more detailed than plain film x-rays; rather than the standard straight-line x-ray beam, CT imaging uses an x-ray beam that moves in a circle around the body to show structures in much greater detail.¹ The scans can be done with or without contrast; contrast is a substance taken either orally or injected within the body, causing a particular organ or tissue to be seen more clearly.²

Virginia Health Information (VHI) reported data on 16 CT scanners in PD 5 for 2023, the latest year for which such data are available. Eleven of these were in acute care hospitals with two more in imaging centers associated with the applicants' freestanding emergency departments (FSED). Three were in freestanding imaging facilities. The 11 hospital-based CT scanners averaged 10,713 procedures per CT scanner, 144.8% of the State Medical Facilities Plan (SMFP) threshold of 7,400 scans per unit. The five freestanding scanners, including the two associated with FSEDs, averaged 3,379 procedures per scanner (45.7% of the SMFP threshold). In aggregate, the 16 diagnostic CT scanners operational in PD 5 in 2023 reported volumes equal to 113.8% of the SMFP standard (**Table 1**).

¹ <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/computed-tomography-ct-scan#:~:text=Computed%20tomography%20is%20commonly%20referred,fat%2C%20organs%20and%20blood%20vessels.>

² Ibid.

Table 1. PD 5 CT Scanners' Utilization, VHI 2023

Facility Name	Total CTs	Total CT Procedures	Procedures / Scanner	% Utilization of 7,400 scan Threshold
Diagnostic CT Scanners				
Carilion Imaging Services - Botetourt CT	1	2,293	2,293	31.0%
Carilion Roanoke Memorial Hospital	8	76,857	9,607	129.8%
Insight Imaging - Roanoke	1	4,273	4,273	57.7%
LewisGale Imaging At Brambleton	1	2,187	2,187	29.6%
LewisGale Hospital Alleghany	1	7,973	7,973	107.7%
LewisGale Medical Center	2	33,017	16,509	223.1%
LewisGale Blue Hills ED	1	3,730	3,730	50.4%
LewisGale Cave Spring ED	1	4,410	4,410	59.6%
2023 Inventory and Utilization	16	134,740	8,421	113.8%
Non-Diagnostic CTs				
LewisGale Medical Center ¹	1			
Authorized, Not Open for Reporting in 2023				
Carilion Roanoke Memorial Hospital ²	1			
Carilion Roanoke Memorial Hospital ³	1			
	2			
Total Authorized PD 5 Diagnostic CT Inventory⁴	18	134,740	7,486	101.2%

1 CT used for radiation therapy simulation
 2 9th CT, housed on Franklin Road per COPN No. VA-04783. Opened January 2025.
 3 10th CT, housed in Crystal Spring Tower per COPN No. VA-04826. Opened May 2025.
 4 Utilization if all 18 authorized diagnostic CT scanners had been operational at the 2023 reported cumulative scan volume

Source: DCOPN Records and VHI 2023 Data

Proposed Project

Lewis-Gale proposes expanding its existing CT service to Hollins ER, an imaging center associated with a new freestanding emergency department at 7645 & 7655 Williamson Road, Roanoke, Virginia, with one CT scanner. The applicant states that the project would be an extension of Lewis-Gale's imaging services and will serve existing Lewis-Gale patients at a location closer to their homes.

The projected capital cost of the proposed project³ is \$1,002,090, approximately 50% of which is attributed to the purchase of the CT scanner and 32% is for direct construction costs (Table 2), about \$300 per BGSF. Capital costs will be funded entirely using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with the proposed project. Construction on the proposed project is anticipated to begin within 17 months of COPN issuance and to be complete within 34 months of COPN issuance.

³ The capital costs reviewed are for that portion of the overall project to develop a freestanding emergency department at are attributable to the CT scanner and its support space, approximately 1,058 building gross square feet (BGSF) of the 12,760 BGSF of the entire freestanding emergency department / imaging center.

Table 2. Lewis-Gale Projected Capital Costs

Direct Construction	\$318,000
Equipment Not Included in Construction Contract	\$560,000
Site Acquisition Costs	\$42,090
Site Preparation Costs	\$51,000
Off-Site Costs	\$9,000
Architectural and Engineering Fees	\$22,000
TOTAL Capital Costs	\$1,002,090

Source: COPN Request No. VA-8823

Project Definition

§32.1-102.1:3 of the Code of Virginia defines a project, in the relevant parts, 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, ...” A medical care facility is defined as “[a]ny facility licensed as a hospital, as defined in § 32.1-123 ...” A FSED is part of a licensed general 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 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;**

The proposed project will be in North Roanoke County, about a mile from Botetourt County at the corner of US Route 11/Williamson Road and Plantation Road/VA Route 115. Williamson Road is a heavily traveled road that provides access between downtown Roanoke and North Roanoke County. The proposed project is also about a mile from US Interstate I-81, a major north(east) to South(west) artery. The applicant states that the proposed location would significantly reduce the amount of time that it currently takes residents from the northern part of the county to access CT imaging and emergency care. Hollins ER is about nine miles (19-minute drive) from Lewis-Gale. The proposed Hollins ER is not served by public transportation, e.g., Valley Metro.

PD 5's population reported in the 2020 census was 281,566 and is projected to grow to 284,571 by 2030, a 1.1% growth rate over ten years. PD 5's projected growth rate is well below the projected rate of 7.9% for Virginia's population. Roanoke County, where the proposed project is located, represents about 35% of the PD 5 population and is projected to grow by 3.3% over the decade, one of only three PD 5 jurisdictions whose population is projected to grow and the only one to grow by more than 2%.

Table 3 PD 5 Population

Locality	2020	2021	2022	2023	2024	2030
Virginia	8,463,009	8,473,157	8,516,841	8,550,197	8,633,690	9,129,002
Roanoke County	96,852	96,546	96,605	96,519	96,497	100,027
Covington City	5,735	5,729	5,650	5,567	5,525	5,434
Roanoke City	99,985	99,883	99,634	99,045	99,504	101,514
Salem City	25,289	25,060	24,924	24,985	25,099	25,519
Alleghany County	15,209	15,151	14,898	14,943	14,984	13,993
Botetourt County	33,605	33,642	33,510	33,466	33,416	33,556
Craig County	4,891	4,885	4,906	4,855	4,766	4,528
PD 5	281,566	280,896	280,127	279,380	279,791	284,571

Source: Weldon Cooper Intercensal Estimates

Table 4 shows that PD 5 has a poverty rate of 12.6%, well above the Virginia average rate of 10.6%, with the poverty rate in Roanoke County, the site of the proposed project, being the second lowest poverty rate at 7.5% in the planning district.

Table 4 PD 5 Poverty Rates

Alleghany County	13.5%
Botetourt County	7.0%
Covington city	16.2%
Craig County	11.8%
Roanoke city	19.9%
Roanoke County	7.5%
Salem city	10.9%
PD 5	12.6%
Virginia	10.6%

Source: Weldon-Cooper Census Data

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;

DCOPN received two letters of support for the proposed project, one from a practice that would utilize the Hollins ER and county fire and rescue department. These letters, in aggregate, expressed the need for additional CT imaging capacity to relieve the strain on capacity of the existing Lewis-Gale scanner and to provide emergency coverage to the northern area of the planning district.

Public Hearing

§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. COPN Request No. VA-8823 is not competing with another project and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing was held.

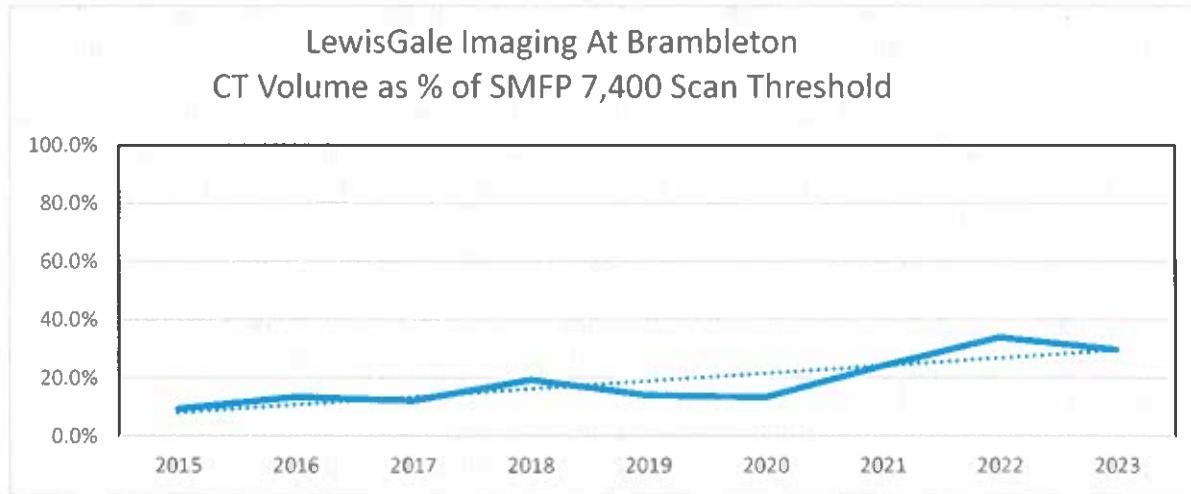
DCOPN provided notice to the public regarding this project inviting public comment on May 15, 2025. The public comment period closed on June 29, 2025. Other than the letters of support referenced above, no members of the public provided comment on the request. There is no known opposition to the project.

(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;

As previously discussed, the most recently published VHI data (2023) reported a 113.8% collective utilization rate (8,421 scans per unit) among all PD 5 CT scanners existing and operational in 2023 (Table 1). The same data reported a collective utilization rate of 45.7% (3,379 scans per unit) among existing CT scanners located at freestanding facilities. Lewis-Gale Imaging CT scanners in freestanding imaging center, including those associated with FSEDs, performed somewhat better with a collective utilization of 46.5% (3,442 scans per scanner), and the CT scanners associated with the two Lewis-Gale FSEDs slightly above that, at 4,070 scans per CT scanner (55.0%), but still well below SMFP threshold for expansion.

Note that the CT scanner located at Lewis Gale Imaging Center at Brambleton has, for at least the most recent 10 years, operated well below the SMFP threshold of 7,400 scans per CT scanner. Utilization of the CT at Lewis Gale Imaging Center at Brambleton has been trending, slowly, upward, (Chart 1), having only risen to 29.6% of the SMFP threshold in 2023. DCOPN suggests that the CT service at the Brambleton location is grossly underutilized, and accordingly, that relocating this scanner to the proposed new freestanding emergency department may be a viable alternative to the proposed project.

Chart 1 LewisGale Imaging At Brambleton



(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 5. Therefore, this consideration is not applicable.

(iv) Any costs and benefits of the project;

As demonstrated in **Table 2**, the total projected capital cost of the proposed project is \$1,002,090, approximately 32% of which is attributed to direct construction. The proposed project will be funded entirely using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with the proposed project.

Lewis-Gale intends to develop the Hollins ER to “meaningfully improve access to essential emergency” services. A FSED does not require COPN authorization. Lewis-Gale further states a need to include a CT scanner at the Hollins ER site to support the FSED and provide CT imaging services to existing Lewis-Gale patients who live closer to Hollins ER than to Lewis-Gale. The applicant reports that in 2024 Lewis-Gale performed 3,125 emergency department CT scans on patients who live closer to the proposed Hollins ER site than to any other Lewis-Gale facility. The applicant estimates that 75% of those cases (2,344 cases) could reasonably be expected to seek care, and CT imagining services, at Hollins ER rather than at Lewis-Gale. This would reduce the per scanner utilization at Lewis-Gale down from 223% to 201% of the SMFP threshold. While it is a meaningful impact, it is not as meaningful as adding a CT scanner at Lewis-Gale.

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

Regarding socioeconomic barriers to access to the applicant’s services, the applicant has provided assurances that Hollins ER will accept all patients, regardless of ability to pay or payment source. The applicant has further stated that Lewis-Gale has a generous charity policy under which medically necessary services are provided at no charge to uninsured patients whose income is at or below 200% of the federal poverty income guidelines. The applicant has also provided assurances that Lewis-Gale will offer discounts for medically necessary care for all patients without insurance who do not otherwise qualify for charity care, regardless of their income level.

According to regional and statewide data regularly collected by VHI, for 2023, the most recent year for which such data is available, the average amount of charity care provided by HPR III facilities was 0.5% (**Table 5**). The applicant included providing charity care at a rate of 0.5% of gross patient revenues as a line item in their application proforma budget (**Table 6**). Lewis-Gale provided charity care at a rate of 0.4% of total gross patient revenues in 2023.

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 CT imaging that is no less than the equivalent average for charity care contributions in HPR III. Pursuant to the 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. 2023 HPR III Charity Care Contributions.

HPR III	Gross Pt Rev	Total Charity Care Provided Below 200%	%
Rehabilitation Hospital of Bristol, LLC	\$ 19,511,661	\$ 485,168	2.5%
Centra Specialty Hospital	\$ 49,263,635	\$ 927,182	1.9%
Carilion Franklin Memorial Hospital	\$ 260,485,310	\$ 3,182,816	1.2%
Carilion Tazewell Community Hospital	\$ 93,201,701	\$ 915,589	1.0%
Carilion Giles Memorial Hospital	\$ 214,444,866	\$ 1,577,250	0.7%
Carilion Medical Center	\$ 4,948,697,558	\$ 39,724,335	0.8%
Carilion New River Valley Medical Center	\$ 955,897,092	\$ 7,639,471	0.8%
LewisGale Hospital-Montgomery	\$ 1,022,426,647	\$ 5,328,382	0.5%
LewisGale Hospital - Alleghany	\$ 283,061,729	\$ 1,151,183	0.4%
LewisGale Hospital Pulaski	\$ 523,904,005	\$ 1,674,632	0.3%
Lewis-Gale Medical Center	\$ 3,302,457,661	\$ 12,305,457	0.4%
Centra Health	\$ 3,324,221,131	\$ 10,826,171	0.3%
Smyth County Community Hospital	\$ 199,838,748	\$ 803,394	0.4%
Bedford Memorial Hospital	\$ 200,565,970	\$ 506,965	0.3%
Norton Community Hospital	Did not report		
Russell County Medical Center	\$ 136,544,998	\$ 349,028	0.3%
Dickenson Community Hospital	\$ 28,592,334	\$ 77,774	0.3%
Johnston Memorial Hospital	\$ 864,558,491	\$ 4,316,555	0.5%
Wellmont Lonesome Pine Mountain View Hospital	\$ 832,222,721	\$ 2,226,897	0.3%
Lee County Community Hospital	\$ 39,718,746	\$ 161,548	0.4%
Buchanan General Hospital	\$ 121,202,254	\$ 98,872	0.1%
DLP Twin County Regional Healthcare	\$ 308,984,072	\$ 68,790	0.0%
Sovah Health-Martinsville	\$ 796,930,431	\$ 94,423	0.0%
Clinch Valley Medical Center	\$ 730,614,306	\$ 298,585	0.0%
Sovah Health-Danville	\$ 1,108,084,476	\$ 129,178	0.0%
Wythe County Community Hospital	\$ 350,271,171	\$ 7,304	0.0%
Ridgeview Pavilion (Bristol Region)	\$ 8,000,972	\$ -	0.0%
Total Inpatient Hospitals:			26
HPR III Total Inpatient \$ & Mean %	\$ 20,723,702,686	\$ 94,876,949	0.5%
Fairlawn Surgery Center, LLC	\$ 7,069,956	\$ 40,683	0.6%
Surgery Center of Lynchburg	\$ 75,066,135	\$ 647,509	0.9%
Roanoke Ambulatory Surgical Center	\$ 38,089,588	\$ 71,166	0.2%
Southwest Virginia Center for Sight	\$ 5,372,878	\$ 6,496	0.1%
Roanoke Valley Center for Sight	\$ 23,125,120	\$ 122,608	0.5%
Roanoke Valley Center for Sight at Oak Grove	\$ 5,361,313	\$ 59,878	1.1%
Martinsville Center for Sight	\$ 7,105,770	\$ 38,570	0.5%
New River Valley Surgery Center	\$ 14,346,732	\$ 67,149	0.5%
Eye Surgery Center of Central Virginia, LLC	\$ 9,412,990	\$ -	0.0%
Blue Ridge Surgery Center	\$ 116,745,790	\$ 13,192	0.0%
Piedmont Day Surgery Center	\$ 3,624,096	\$ -	0.0%
Total Outpatient Hospitals:			11
HPR III Total Outpatient Hospital \$ & Mean %	\$ 305,320,368	\$ 1,067,251	0.3%
Total Hospitals:			37
HPR III Total Hospital \$ & Mean %	\$ 21,029,023,054	\$ 95,944,200	0.5%

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;

DCOPN did not identify any other factors as may be relevant to the determination of public need for the proposed project not addressed elsewhere in this staff analysis report.

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

The State Medical Facilities Plan (SMFP) contains criteria/standards for the establishment of specialized centers for MRI services. They are as follows:

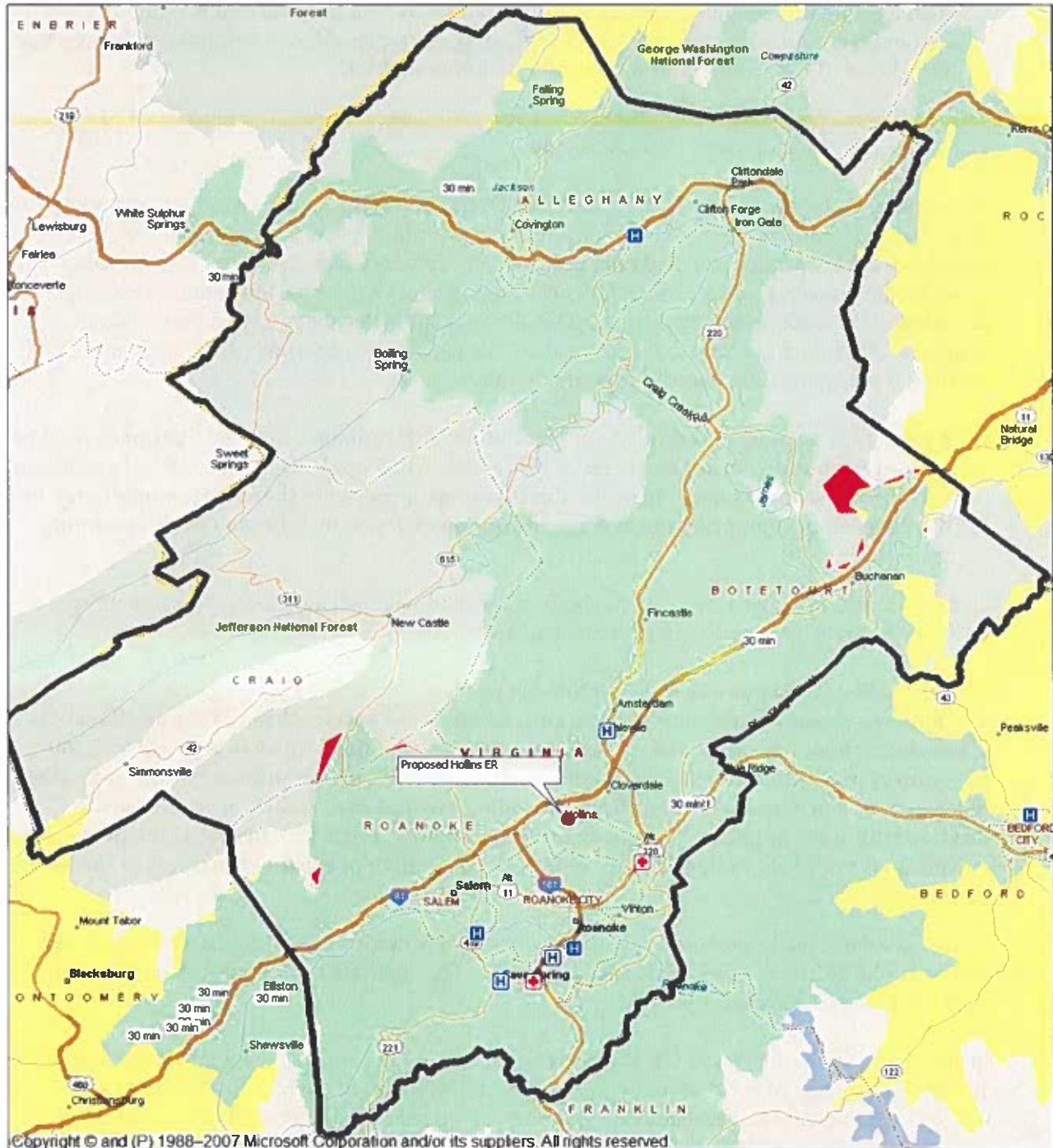
Part II.
Diagnostic Imaging Services
Article 1.
Criteria and Standards for Computed Tomography

12VAC5-230-90. Travel Time.

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

The heavy black line in **Figure 1** identifies the boundary of PD 5. The white squares with the blue "H" signs mark the locations of existing CT scanners located in PD 5 in freestanding imaging centers. The red crosses note the location of existing FSEDs with CT scanners. The blue squares with the white "H" sign mark the location of existing hospitals with CT scanners. The red circle notes the location of the proposed project. The green shaded area in Figure 1 illustrates the area of PD 5 and the surrounding area that is within a 30-minute drive of existing CT services. The yellow shaded area illustrates the area of PD 5 and the surrounding area that is within a 30-minute drive of CT scanners in surrounding planning districts. The red shaded areas are new areas that would be within a 30-minute drive of the proposed facility that is not already within a 30-minute drive of an existing CT scanner. Given the amount of shaded area, and that the PD 5 population is concentrated in the Roanoke City/Salen City area in the southern portion of the planning district, it is reasonable to conclude that CT services are currently available within 30-minutes normal driving time, one way, under normal conditions of 95% of the population of PD 5. Approval of the proposed project would not significantly improve geographic access to CT services in PD 5.

Figure 1. Planning District 5 Location and Drive Time to CT Imaging Services



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.

The applicant is proposing to establish a new fixed site by including a CT scanner in a FSED Lewis-Gale is developing in northern Roanoke County.

The applicant's project is submitted under 12VAC5-230-110, which authorizes hospitals performing more than 7,400 procedures per CT scanner to be approved for a new CT scanner either at the hospital 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." DCOPN concludes that the proposed freestanding emergency department is licensed under, and an extension of, the general hospital and that 12VAC5-230-110 is the appropriate standard to apply for this.

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 T scanners in such health planning district.

The CT scanner at Lewis-Gale used solely for simulation with radiation therapy treatment was excluded from the volume-based need calculations.

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.

As discussed above, the proposed freestanding emergency department functions as an extension of and under the license of Lewis Gale Medical Center. The applicant cites an institutional specific need to expand its current CT service.

In aggregate, the 16 diagnostic CT scanners operational in PD 5 in 2023 reported volumes equal to 113.8% (an average of 8,421 scans per operational CT scanner) of the SMFP standard (Table 1). If the 2023 scan volume had been applied to the 18 authorized CT scanners and not just the 16 operational scanners in 2023 the average scan volume for each of the 18 scanners would still have been 7,486 (101.2%) still exceeding the SMFP threshold of 7,400 scans. Accordingly, DCOPN concludes that the applicant has satisfied this standard.

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

The applicant does not seek to add or expand mobile CT services. Accordingly, this standard is not applicable to the proposed project.

12VAC5-230-130. Staffing.

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

The applicant has provided assurances that the proposed project would be under the direction or supervision of one or more qualified physicians. Specifically, CT services at Hollins ER will be under the direction of Radiology Associates of Roanoke.

The SMFP also contains criteria/standards at 12VAC5-230-80 for when institutional expansion is needed that apply when a planning district has an excess supply of [CT] services. Given the high utilization volume of the existing and authorized CT scanners in PD 5, there is no excess supply of CT scanners in the PD. Therefore, the 12VAC5-230-80 Institutional Expansion section does not apply.

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;**

The applicant has cited an institutional need to expand its existing CT services in an effort to decompress its main campus. As a result, the primary patient population this project would serve is patients who have already chosen Lewis Gale as their care provider. A secondary patient population for this project is those individuals who would otherwise travel to Lewis Gale—the closest hospital to the proposed project—for emergency services. For these reasons, DCOPN contends that the proposed project is not intended to, and is unlikely to, foster institutional competition that would benefit the area to be served.

- 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;**

As already discussed, existing CT scanners in PD 5 operated at a collective utilization of 113.8% in 2023 (Table 1).

The applicant has five of the eight facilities that offer CT services in PD 5 and 6 of the 16 (37%) diagnostic CT scanners. Overall, the most recent data demonstrates that the average utilization rate for all Lewis-Gale CT scanners in PD 5 was 115.6% and 112.7% for the non-Lewis-Gale controlled CT scanners.

The site proposed for the Hollins ER is just over eight miles (24-minute drive) from the next closest non-Lewis-Gale CT scanner (Carilion Roanoke Memorial Hospital). It is unlikely that the proposed project will have a negative impact on existing PD 5 providers.

The applicant states that Hollins ER will provide copies of records to other providers as necessary for appropriate follow-up and continuity of care and as permitted by applicable health records privacy laws. Additionally, DCOPN contends that HCA facilities have adequately demonstrated the ability to share staff and equipment. Areas such as the business office, materials management, and central scheduling have been formally consolidated among the HCA hospitals in Southwest Virginia. The HCA business office in Central Virginia also provides services to HCA facilities in Southwest Virginia. In addition, informal sharing of staff, equipment, and supplies occurs on a routine basis as HCA hospitals respond to fluctuation demand and patient needs.

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

The Pro Forma Income Statement (**Table 6**) provided by the applicant projects a net profit of \$199,1643 by the end of the first year of operation and a net profit of \$220,811 by the end of year two, indicating that the proposed project is financially feasible both in the immediate and the long-term. The total projected capital cost of the proposed project is \$1,002,090, with approximately 32% of that cost being attributed to direct construction (**Table 2**). Capital costs will be funded entirely using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with the proposed project.

Table 6. Hollins ER CT Scanner Pro Forma Income Statement

	Year 1	Year 2
Gross Revenue	\$14,035,195	\$14,889,939
Charity Care	\$70,176	\$74,450
Other Deductions from Revenue	\$12,561,499	\$13,281,826
Net Patient Services Revenue	\$1,403,520	\$1,533,663
Total Operating Expenses	\$1,204,356	\$1,312,852
Excess Revenue Over Direct Operating Expenses	\$199,164	\$220,811

Source: COPN Request No. VA-8823

The applicant anticipates the need to hire 4.8 full-time employees (FTEs) to staff the CT scanner proposed for the Hollins ER. These employees are as follows: 0.2 administration-business office employees; 4.6 radiologic technologists. The applicant is an established provider of CT services

and has a well-developed and effective recruitment and employee retention program. Taken together with the small number of employees needed for this project, DCOPN does not believe the applicant will have difficulty filling the required positions or that doing so will have a negative impact on other area healthcare providers.

- 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; and (iv) At the discretion of the Commissioner, any other factors as may be appropriate; and**

The proposed project does not offer the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services. However, the proposed project does increase the potential for provision of services on an outpatient basis, while helping to decompress the over utilized CT scanners located on the Lewis Gale main campus and servicing the freestanding emergency department. DCOPN did not identify any other factors that have not been addressed elsewhere in this staff analysis report to bring to the attention of the commissioner.

- 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 for citizens of the Commonwealth, including indigent or underserved populations.**

Neither Hollins ER nor Lewis Gale is or is associated with a teaching hospital or medical school of a public institution of higher learning. Lewis-Gale has affiliation agreements for clinical rotations with 26 health professional education programs.

DCOPN Findings and Conclusions

Lewis Gale proposes expanding its existing CT services to Hollins ER, a new freestanding emergency department under development that is proposed to contain one CT scanner. The projected capital cost of the proposed project is \$1,002,090, with approximately 32% of that cost being attributed to direct construction of the CT space. The proposed project will be funded entirely using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with the proposed project. Construction on the proposed project is anticipated to be complete within 34 months of COPN issuance. The Pro Forma budget provided by the applicant projects a net profit of \$220,811 by the end of the second full year of operations, indicating that the proposed project would be profitable both in the immediate and the long-term.

The applicant budgeted to provide charity care in the amount of 0.5% of total gross patient revenues derived from CT services at the proposed new facility. While this amount is at the HPR III average, and slightly above Lewis-Gale Medical Center's charity rate of 0.4% in 2023. 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 CT imaging that is at a rate no less than the equivalent average for charity care contributions in HPR III, 0.5% in the relevant reporting period. 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.

The applicant cites an institutional need to expand based on the overutilization of existing CT scanners on the main campus. For 2023, the average utilization of existing diagnostic CT scanners operated at a collective utilization of 113.8% (8,421 procedures per scanner), above the SMFP threshold for expansion. However, DCOPN concludes that underutilized inventory exists within the HCA Virginia Health System and that relocating the underutilized scanner from Lewis Gale Imaging at Brambleton may be a viable alternative to the proposed project.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **conditional approval** of the Lewis-Gale Medical Center's COPN Request number VA-8823 to expand its existing CT service to a freestanding emergency department at 7645 & 7655 Williamson Road, Roanoke, Virginia with one CT scanner for the following reasons:

1. The proposed 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. Approval of the proposed project is not likely to have a significant negative impact on the utilization, costs or staffing of other area providers of CT services.
3. The proposed project is financially feasible in the immediate and the long-term.
4. There is no opposition to the proposed project.

DCOPN's recommendation is contingent upon Lewis Gale Medical Center, LLC's agreement to the following condition:

Lewis-Gale Medical Center, LLC will provide CT imaging services at Hollins ER 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 will facilitate the development and operation of primary medical care services to medically underserved persons in PD 5 in an aggregate amount equal to at least 0.5% of Lewis-Gale Medical Center's Hollins ER gross patient revenue derived from CT imaging services. 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. Lewis-Gale Medical Center, LLC 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 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.

Lewis-Gale Medical Center, LLC will provide CT imaging services to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et seq. Additionally, Lewis-Gale Medical Center, 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.

