VIRGINIA DEPARTMENT OF HEALTH Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis Report

January 19, 2023

COPN Request No. VA-8669 Holston Medical Group Duffield, Virginia Establish a specialized center for CT imaging with one CT scanner

COPN Request No. VA-8676 Wellmont Medical Associates, Inc. Norton, Virginia Establish a specialized center for CT imaging with one CT scanner

Applicants

Holston Medical Group, P.C. (HMG) is a wholly owned, for-profit Tennessee professional corporation formed on January 9, 1989 in Sullivan County, Tennessee originally as Indian Valley Medical Group. The proposed project, Duffield Imaging Center (Duffield Imaging) would be located in the town of Duffield, in Scott County, Virginia, in Health Planning Region (HPR) III, Planning District (PD) 1.

Wellmont Medical Associates, Inc. (WMA) is a non-profit Tennessee Corporation formed December 17, 2008 in Sullivan County Tennessee. Ballad Health is the sole member of WMA. The proposed project, Ballad Health Imaging Center – Norton (Ballad Imaging) would be located in the City of Norton, Virginia, in HPR III, PD 1.

Background

HMG has leased the property at 121 Advanced Technology Drive, Duffield, Virginia since March 31, 2016, and operates a primary care practice and a physical therapy / outpatient rehabilitation practice at that location.

In September 2022 WMA and partner Wellmont Health System (WHS) filed a letter of intent to lease the property at 1490 (Suite C) Park Avenue, Norton, Virginia, contingent on successfully obtaining a certificate of public need (COPN) authorizing the establishment of a specialized center for computed tomography (CT) imaging for WHS to construct the referenced imaging center.

In 2018, pursuant to the 30 October 2017 Order and Letter Authorizing a Cooperative Agreement Wellmont Health System and Mountain States Health Alliance merged to form Ballad Health. As a result of the merger Ballad Health became the sole provider of inpatient health care, as well as CT imaging, in southwest Virginia. Likewise, Tennessee authorized a Certificate of Public Advantage allowing the two systems to merge in Tennessee. The resulting Ballad Health is, subject to the active supervision of Virginia and Tennessee, insulated from antitrust action in the formation of a monopoly in inpatient care.

In July 2021 Ballad Health re-opened a critical access hospital, closed since October 2013, in Lee County, Virginia. The new six bed Lee County Community Hospital includes a CT scanner as well as other services vital to the well-being of the citizens of Lee County.

Division of Certificate of Public Need ("DCOPN") records show that, excluding CT scanners used solely for simulation with radiation therapy treatment, there are currently 3 COPN authorized fixed CT scanners and no mobile CT scanner sites (**Table 1**) in PD 1.

				Reported CT Volume Per Authorized Scanner				
		Scanners	2018	2019	2020	2021	2022 ³	
Lee County Community Hospital	Pennington Gap	1					3,947	
Lonesome Pine Hospital ¹	Big Stone Gap	1	12,000	11,102	5,677	5,658	5,340	
Mountainview Medical Center ²	Norton	0			1,764			
Norton Community Hospital	Norton	1	10,782	10,376	12,665	9,567	12,986	
Total		3	22,782	21,478	20,106	15,225	22,273	
Average Volume Per CT Scanner			7,594	7,159	6,702	5,075	7,424	

Table 1. PD 1 COPN Authorized CT Units*

Source: DCOPN records and Ballad Health

1 Lonesome Pine Hospital reported 2 CT scanners in 2018 and 2019, with 1 authorized scanner, the second CT scanner was at Mountain View Hospital and reported collectively prior to 2020.

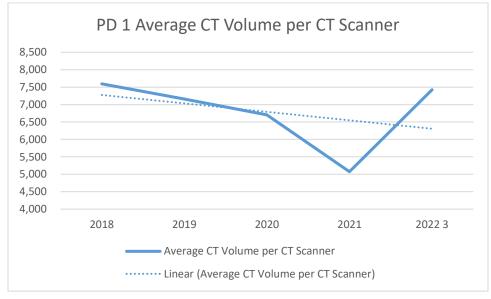
2 Prior to decommissioning the Mountain View Hospital CT in 2019 its patient volume was reported collectively with Lonesome Pine Hospital's.

3 Self-Reported by Ballad Health, Not Through VHI

* All authorized CT scanners in PD 1 are fixed site scanners

Chart 1 shows that the PD 1 CT scanner utilization reported in Table 1 has a downward trend over the past five years. While the significant impact on utilization in 2020 and 2021 reflects the effect of the curtailment of elective procedures during the height of the COVID-19 pandemic, the patient volume reported by Ballad Health for 2022 essentially shows a return to pre-pandemic levels.

Chart 1



Proposed Projects

VA-8669 – HMG

HMG proposes to establish CT services at its Duffield, Virginia practice location through the addition of one fixed 16-slice CT scanner. The total capital and financing cost of the proposed project is \$92,000 (**Table 2**). The applicant states that they anticipate that they will pay for the project with accumulated reserves.

Table 2. COT IN Request VA-0009 Capital and Fillan	ung	Custs
Direct construction	\$	268,730
Equipment not included in the construction contract	\$	150,000
Lease	\$	249,283
Architectural and engineering	\$	16,430
Taxes during construction	\$	78,226
Total	\$	762,669

Table 2. COPN Request	VA-8669 Capital and Financing Costs
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Source: COPN Request number VA-8669

<u>VA-8676 – WMA</u>

WMA proposes to establish CT services, along with other non-COPN regulated imaging services, at the Ballad HealthPlex location in Norton, Virginia through the addition of one fixed 64-slice¹ CT scanner. The Ballad HealthPlex is an existing, multidisciplinary practice site across the street from Ballad Norton Community Hospital. The total capital and financing cost of the proposed project is \$2,485,505 (**Table 3**). The applicant states that they anticipate that they will pay for the project with accumulated reserves, therefore there will be no financing costs.

¹ December 22, 2022 letter of opposition from Emily Towey to COPN Request No. VA-8669

	-8 ~	0000
Direct construction	\$	878,700
Equipment not included in the construction contract	\$	750,000
Lease	\$	700,000
Architectural and engineering	\$	156,805
Total	\$	2,485,505

Table 3. COPN Request- VA-8676 Capital and Financing Costs

Source: COPN Request number VA-8676

Project Definition

COPN Request numbers VA-8669 and VA-8676

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

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

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

1. The extent to which the proposed 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;

<u>VA-8669 – HMG</u>

The proposed Duffield facility is located just off US-58 / US-421, a major east-west highway, near its intersection with the north-south US-23. No municipal public transportation is available in Duffield, but taxi services are available. Additionally, the applicant states that the U.S. Department of Transportation offers access to government assisted ride sharing programs that are coordinated by HMG's care coordination team.

<u>VA-8676 – WMA</u>

The proposed Norton facility is located just off Alternate US-58, a major east-west highway, near its intersection with the north-south Business US-23. The proposed imaging center will be located in the Ballad HealthPlex, across the street from Ballad Norton Community Hospital. The applicant makes no reference to any public transportation availability in the City of Norton.

The population of PD 1 is projected to experience a small decline in population (88 persons, -0.01% annually) between 2020 and 2030 (Table 4). All jurisdictions within PD 1, except for Lee County, are projected to experience either no change or a modest decline. Scott County, the proposed location for HMG's COPN Request VA-8669, will account for 24.3% of PD 1's 2030 population. Norton City, along with Wise County, will account for a combined 47% of PD 1's 2030 population.

	2010	2020	2030	Avg Ann Rate 2020-2030	2030 % of PD
City of Norton	3,958	3,928	3,928	0.00%	4.4%
Lee County	25,587	24,775	25,657	0.35%	28.7%
Scott County	23,177	22,346	21,764	-0.26%	24.3%
Wise County	41,452	38,554	38,166	-0.10%	42.6%
PD 1 Total	94,174	89,603	89,515	-0.01%	
Virginia	8,001,024	8,744,273	9,546,958	0.88%	

Table 4. PD 1 Population

Source: Weldon Cooper

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;

<u>VA-8669 – HMG</u>

Ten letters of support were received for the proposed CT imaging facility in Duffield, Virginia. Among others, letters were received from leadership in Wise, Scott, and Dickenson Counties, from the LENOWISCO Planning Commission, two physician's practices (other than HMG), a patient, and from Del. Kilgore. The letters generally supported the improved geographic access to CT imaging and the introduction of competition in an area where none exists for CT imaging services the proposed project would bring.

One letter of opposition was received from WMA, the competing applicant, arguing that there is no supported need for the addition of two additional CT scanners in PD 1. In comparing the projects WMA argues the CT unit proposed by WMA was technically superior to that proposed by HMG and that the WMA scanner will be in a more populated area.

<u>VA-8676 – WMA</u>

Six letters of support were received for the proposed CT imaging facility in Norton, Virginia. Among others, letters were received from leadership in Wise County, a patient, two Ballad Health physicians and Del. Kilgore. In general, the letters cite that the WMA project would introduce non-hospital-based CT imaging to the area, allowing patients access to a generally lower cost alternative to imaging services, as compared to the existing hospital-based services.

There is no known opposition to the WMA requested project.

Public Hearing

A public hearing was required due to there being two competing applicants in the review (VA Code § 32.1-102.6). DCOPN conducted the required public hearing in person on December 16, 2022 in Big Stone Gap, which is in a jurisdiction adjacent to the jurisdiction

where each of the proposed projects would be located. A total of 25 individuals signed into the public hearing, seven of whom indicated their support for the HMG request and 15 indicated their support for the WMA request. Ten of the individuals attending indicated they were opposed to the HMG request and no attendee indicated opposition to the WMA request. Seven attendees spoke, three in support of the HMG request and four in support of the WMA request. Three of those speaking in support of the WMA request also spoke in opposition to the HMG request. Nobody expressed opposition to the WMA request.

(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;

The status quo would require patients in need of CT imaging to either have their scans performed in an inpatient hospital or to travel out of the planning district, or out of state, for scanning in an outpatient facility. Imaging in outpatient facilities is typically less expensive and third-party payors are either encouraging or requiring services to be provided in outpatient facilities when available. The status quo is not a preferable alternative.

Approval of only one of the requests is a reasonable alternative to approval of both proposed projects. The current PD 1 inventory of three scanners is adequate and presently meets the current demand within the PD. However, the three existing CT scanners are concentrated along the US Route 58 corridor along the western edge of the planning district.

The introduction of mobile CT imaging at one or more sites in PD 1 may be an option to better distribute CT imaging services throughout the PD. However, part time availability, the added expenses and time of moving the scanner, and weather-related interruptions in the mountains reduce the benefits of mobile imaging, especially if adequate justification exists for the establishment of fixed site scanner(s).

There is no appropriate clinical alternative to CT scanners that could be implemented that would meet the public's needs.

(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 1. Therefore, this consideration is not applicable to the review of the proposed project.

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

Both requests are generally consistent with other similar COPN requests to establish centers for CT imaging with respect to square footage involved. The construction cost per square foot is extremely varied. As Table 5 illustrates the two proposed projects are generally consistent with the compared projects, with the direct construction cost per square foot for

the HMG request being the least expensive of the compared projects. HMG's equipment cost is also the lowest of the compared projects and reflects the applicant's intention to purchase a 16-slice CT scanner. The applicant has assessed that a 16-slice CT scanner is sufficient to meet the needs of patients in this rural area, with recognition that more advanced imaging capability is available elsewhere in the planning district, or in nearby Tennessee should it be required.

Applicant	Request / COPN #	Project Square Feet	Direct Construction	Construction Per Square Foot	Equipment Cost
HMG	VA-8669	1,005	\$ 268,730	\$ 267	\$ 150,000
WMA	VA-8676	2,000	\$ 7,903,000	\$ 3,952	\$ 2,855,000
HCA Health Services of Virginia	VA-04811	1,569	\$ 7,903,000	\$ 5,037	\$ 2,855,000
IFRC	VA-04798	1,048	\$ 750,564	\$ 716	\$ 753,316
Montgomery Regional Hospital	VA-04803	1,058	\$ 8,714,000	\$ 8,236	\$ 2,855,000

Table 5. Project Cost Comparison

Source: COPN Applications

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

In accordance with section 32.1-102.4.B of the Code of Virginia, should the proposed project(s) receive approval, the project(s) 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 Code of Virginia language any COPN issued for this/these project(s) will also be conditioned on the applicant's agreement to accept patients who are the recipients of Medicare and Medicaid.

VA-8669 – HMG

HMG has committed to provide services to patients who are the recipients of Medicare and Medicaid.

<u>VA-8676 – WMA</u>

Ballad Health has a history of accepting patients under Medicare and Medicaid reimbursement plans. WMA, as a wholly owned subsidiary of Ballad Health, would be expected to do likewise, however that was not made clear within the application. WMA has budgeted providing charity care at a rate of 1.0% of CT imaging gross patient revenue.

According to regional and statewide data regularly collected by VHI, for 2020, the average amount of charity care provided by the facilities in HPR III that reported such charity care for that year was 0.7% of all reported total gross patient revenues (**Table 5**). As neither applicant has previously been assigned a charity care condition, VHI does not have any data on the charity care provided by the applicants. In accordance with section 32.1-102.4.B. of the Code of Virginia, should the proposed projects receive approval, approved COPN requests will be conditioned on the applicant's agreement to provide a level of charity.

Table 6. Health Planning Region III Charity Care

	2020 at 200%						
HPR III	Gross Pt Rev	Charity Care below 100% of the Federal Poverty Level	Charity Care between 100% and 200% of the Federal Poverty Level	Total Charity Care Provided Below 200%	ICTF Payments to and from (-)	Adjusted Charity Care	%
Carilion Franklin Memorial Hospital	\$146,159,934	\$3,708,842	\$0	\$3,708,842	\$0	\$3,708,842	2.5%
Bedford Memorial Hospital	\$122,377,242	\$2,291,732	\$65,478	\$2,357,210	\$0	\$2,357,210	1.9%
Dickenson Community Hospital	\$25,321,849	\$358,606	\$107,116	\$465,722	ψũ	\$465,722	1.8%
Carilion Tazewell Community Hospital	\$57,945,546	\$956,508	\$0	\$956,508	\$0	\$956,508	1.7%
Carilion Giles Memorial Hospital	\$107,478,905	\$1,438,902	\$0	\$1,438,902	\$0	\$1,438,902	1.3%
Russell County Medical Center	\$121,070,842	\$1,391,692	\$137,640	\$1,529,332	\$0	\$1,529,332	1.3%
Wellmont Lonesome Pine Mt. View Hospital	\$372,115,538	\$4,558,248	\$0	\$4,558,248	\$0	\$4,558,248	1.2%
Carilion Medical Center	\$3,983,507,417	\$47,514,964	\$0	\$47,514,964	\$0	\$47,514,964	1.2%
Carilion New River Valley Medical Center	\$711,175,865	\$8,034,717	\$0	\$8,034,717	\$0	\$8,034,717	1.1%
Johnston Memorial Hospital	\$855,313,389	\$6,173,990	\$1,641,188	\$7,815,178	\$0	\$7,815,178	0.9%
Norton Community Hospital	\$311,397,944	\$2,148,231	\$641,679	\$2,789,910	\$0	\$2,789,910	0.9%
Smyth County Community Hospital	\$198,825,769	\$943,274	\$803,530	\$1,746,804	\$0	\$1,746,804	0.9%
Centra Health	\$2,649,888,465	\$20,343,916	\$625,967	\$20,969,883	\$0	\$20,969,883	0.8%
Montgomery Regional Hospital	\$680,834,380	\$5,052,836	\$0	\$5,052,836	\$0	\$5,052,836	0.7%
Lewis-Gale Medical Center	\$2,312,565,268	\$16,178,913	\$23,383	\$16,202,296	\$0	\$16,202,296	0.7%
Pulaski Community Hospital	\$346,826,376	\$2,062,032	\$78,287	\$2,140,319	\$0	\$2,140,319	0.6%
Alleghany Regional Hospital	\$189,090,272	\$708,115	\$150	\$708,265	\$0	\$708,265	0.4%
Twin County Regional Hospital	\$222,632,986	\$0	\$649,064	\$649,064	\$0	\$649,064	0.3%
Clinch Valley Medical Center	\$520,600,957	\$846,309	\$100,248	\$946,557	\$0	\$946,557	0.2%
Buchanan General Hospital	\$99,508,254	\$0	\$105,669	\$105,669	\$0	\$105,669	0.1%
Memorial Hospital of Martinsville & Henry County	\$668,028,626	\$294,122	\$288,834	\$582,956	\$0	\$582,956	0.1%
Wythe County Community Hospital	\$235,991,599	\$93,569	\$0	\$93,569	\$0	\$93,569	0.0%
Danville Regional Medical Center	\$910,930,415	\$384,656	\$207,123	\$591,779	-\$19,999,079	-\$19,407,300	-2.1%
Lee County Community Hospital ¹							
Mountain View Regional Medical Center							
Total Facilities:							23
HPR III Median							0.9%
HPR III Total \$ & Mean%	\$15,849,587,838	\$125,484,174	\$5,475,356	\$130,959,530	-\$19,999,079	\$110,960,451	0.7%

Source: VHI

1 Lee County Community Hospital began operations in July 2021

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

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

3. The extent to which the 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 State Medical Facilities Plan (SMFP). The SMFP contains criteria/standards for the establishment or expansion of CT 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.

<u>VA-8669 – HMG</u>

The HMG proposed project would increase access to patients not currently within a thirty-minute drive under normal driving conditions of CT services. Specifically, the towns/populated areas of Weber City, Gate City, Stanleytown, Clinchport, and Verdi (combined population of approximately 4,990 or approximately 5.6% of the 2020 population of PD 1) as well as additional area, would be added to those within a thirty-minute drive under normal driving conditions of CT services. At least 95% of the population of Planning District 1 is not currently within a thirty-minute drive under normal driving conditions of CT services.

VA-8676 - WMA

As the proposed WMA site is adjacent to the existing Norton Community Hospital CT site, no new area within a 30-minute drive under normal conditions will be added.

Currently, excluding CT scanners used solely for simulation with radiation therapy treatment, there are 3 COPN authorized CT scanners in PD 1. The heavy black line in Figure 1 is the boundary of PD 1. The blue H icons indicate facilities that currently offer fixed CT services (including a hidden "H" in Norton, behind the white "H" representing the WMA project location). The white H icons indicate the locations of the facilities proposed by COPN Request Nos. VA-8669, and VA-8676. The grey shading illustrates the area that is within a thirty-minute drive under normal driving conditions of CT service providers in locals outside PD 1. The light blue shading is the area that is within a 30-minute drive under normal conditions of existing CT providers within PD 1. The pink shading is the new area in PD 1 that will be within a 30-minute drive under normal conditions if the HMG request is approved.

Figure 1

Source: DCOPN generated

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.

<u>Calculated Needed Fixed CT Scanners in PD 1 2 </u> COPN authorized CT scanners = 3

Calculated Needed CT scanners = $21,478^{-3}$ scans in the PD / 7,400 scans / scanner = 2.9 (3) scanners needed

PD 1 Calculated Need = 3 CT scanners

PD 1 Calculated Surplus = 0 CT scanners

² Table 1 data

³ 2019 utilization as reported to VHI is used as the relevant reporting period. While data is available for years up to and including 2021, 2019 is the last year for which CT utilization data is not artificially depressed in response to the COVID-19 pandemic.

Fixed CT Utilization in PD 1

As noted in **Table 1**, the utilization of existing CT scanners in the planning district was 7,159 in 2019, the pre-pandemic level, resulting in a rate of 96.7% of the 7,400 procedures per scanner necessary to introduce CT scanning services to a new location under this section of the SMFP. If the Ballad Health reported 2022 per scanner volume of 7,424 scans is used the resulting rate would be 100.3%. Therefore, PD 1 CT scanner volume is 24 scans more than the standard for three scanners. Therefore, using the Ballad Health report CT volume for 2022, there is a need for one additional CT scanner in PD 1.

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

DCOPN has excluded existing CT scanners used solely for simulation prior to the initiation of radiation therapy from its inventory and average utilization of diagnostic CT scanners in PD 1 with respect to the proposed projects.

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.

Not applicable. Neither of the proposed projects seek to expand fixed site CT services.

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. Neither of the proposed projects seek 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.

VA-8669 - HMG and VA-8676 - WMA

Both applicants provide assurances that the CT imaging service will be under the direction of a qualified physician.

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;

VA-8669 - HMG

All three existing diagnostic CT scanners in PD 1 are operated by Ballad Health in three different acute care hospitals; the closest Virginia CT providers outside of PD 1 are also in Ballad Health hospitals. Approval of COPN Request number VA-8669 would introduce the only CT scanner competing with Ballad Health in PD 1. As discussed previously, the establishment of CT imaging services in Duffield, Virginia would also make the imaging service available within the 30-minute drive time standard to a substantial number of the residents of Scott County who currently live more than 30-minutes away of a CT imaging service. Additionally, the proposed CT service is to be in a free-standing, non-hospital affiliated center, making that lower cost venue available to the planning district.

<u>VA-8676 – WMA</u>

WMA proposes to establish a CT imaging facility in a free-standing, non-hospital affiliated center, making that lower cost venue available to the planning district. While WMA's proposed imaging facility would not be hospital based, it would be under the control of Ballad Health, the current sole operator of CT imaging in PD 1. Therefore the WMA request would not introduce any institutional competition to PD 1.

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;

<u>VA-8669 – HMG</u>

HMG is a physician practice group with offices in southwest Virginia and northeast Tennessee. HMG currently does not operate a COPN authorized facility in Virginia. As a major physician practice group throughout Ballad Health's service area HMG has a strong relationship with Ballad Health, as well as being competitors in some services.

HMG reports that in 2022 over 2,000 of HMG's Virginia patients were referred to HMG imaging facilities in Tennessee for CT scans. While an HMG CT facility in Duffield is likely to have some negative impact on patient volume at Virginia based Ballad Health hospitals it is not expected to be significant.

<u>VA-8676 – WMA</u>

WMA is owned by Ballad Health. Any scan performed at the WMA Norton CT scanner would be a scan that would have been performed at a Ballad Health hospital, likely Norton Community Hospital. In 2019 (prior to any CT imaging reduction resulting from the COVID-19 pandemic) the CT scanner at Norton Community Hospital operated at 140.2% of the SMFP volume standard of 7,400 scans (Table 1). In 2022 Ballad Health reported (but not available from publicly available data at VHI) that the Norton Community Hospital CT scanner operated at 175.5% of the SMFP volume standard. The applicant argues that the project not only meets a need for a non-hospital based, outpatient, CT imaging service, but that it will also offload outpatients from the busy hospital-based CT scanner.

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;

<u>VA-8669 – HMG</u>

The proposed project is among the least expensive projects requested recently to establish a CT outpatient imaging facility, due in large part to the selection of a 16-slice CT scanner. HMG will pay for the project through accumulated reserves, avoiding any cost to finance the project. HMG expects to perform 3,108 CT scans per year for the first two years of operation, gradually increasing to 3,125 by year five. HMG estimates the CT scanner in Duffield will be profitable by the fifth year of operation.

HMG will hire seven new staff to operate the CT imaging facility (two business staff, one RN, one LPN, and three radiologic technologists). In general, there is a shortage of licensed health care providers (RNs, LPNs, and radiologic technologists), a fact that may be even more significant in rural areas such as Duffield, Virginia. HMG does have experience in recruiting staff for their imaging centers in Tennessee.

<u>VA-8676 – WMA</u>

The cost to develop the CT imaging facility is reasonable (Tables 3 and 5) particularly when compared to similar requests. WMA will pay for the project through accumulated reserves, avoiding any cost to finance the project. WMA expects to perform 4,724 CT scans in the first year and 4,960 CT scans in the second year of operation, showing a profit the first year of operation. WMA expects some portion of the patient volume at the WMA facility will be from patient currently seen at the Norton Community Hospital CT scanner, reducing the volume, and revenue at the hospital-based CT scanner.

WMA will hire two new staff to operate the CT imaging facility (one business staff, and one radiologic technologist). In general, there is a shortage of licensed health care providers. WMA may be able to rely on the experience and recruiting capability of their parent, Ballad Health.

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

VA-8669 - HMG and VA-8676 - WMA

Both requests propose what are generally referred to as "freestanding" outpatient imaging centers, in these cases offering CT imaging as well as other imaging modalities not subject to COPN review. CT imaging provided in non-hospital-based outpatient centers is generally less costly to perform, having avoided the hospital overhead costs, and as such are less expensive for third party payors.

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.

VA-8669 – HMG and VA-8676 – WMA

Not applicable. Neither applicant is affiliated with a teaching hospital associated with a public institution of higher education or a medical school in the area to be served.

DCOPN Staff Findings and Conclusion

There are two competing applicants for the establishment of a freestanding, non-hospital based, outpatient CT imaging center in PD 1, one in Duffield (COPN Request number VA-8669 from HMG) and one in Norton (COPN Request number VA-8676 from WMA). Currently there are three diagnostic CT scanners in PD 1, all are in hospitals owned by Ballad Health. Using the last publicly available data (VHI) that reflects the demand for CT imaging unaffected by service reductions due to the COVID-19 pandemic (2019) there is a need for three CT scanners in PD 1. Given that, except for Lee County, the population of PD 1 is stable or slowly declining, the current inventory of CT scanners, short of a demonstrated institutional need by an existing provider, is sufficient to meet the volume demand of the population of PD 1.

Considering CT utilization data provided by Ballad Health, the owner of all three existing CT scanners in PD 1, is reasonable since they have firsthand access to all providers in the planning district and the data reflects what should be provided to VHI for 2022. CT utilization for 2022 marginally supports the need for a fourth CT scanner in PD 1. WMA repeatedly states that there is a need for only one additional CT scanner.

The existing inventory of hospital-based CT scanners in PD 1 is concentrated along the western edge of the planning district, and the CT scanners in neighboring PDs 2 and 3 are more than a

30-minute drive from the residents of southeast Scott County (PD 1). These Scott County residents account for at least 5% of the population of PD 1. While the existing CT scanners are appropriately placed in the more densely populated areas of the planning district, and are serving the inpatient hospitals, it has resulted in somewhat of a mal-distribution of CT services in the PD.

All the existing CT scanners in PD 1 are hospital-based, which is typically a more expensive venue than in freestanding outpatient centers. Both applicants propose to establish a freestanding, outpatient CT imaging center, one in Norton, across the street from the CT scanner located at Norton Community Hospital (WMA) and one in Duffield, in Scott County. As such, if either or both requests are approved, a lower cost option for local access to CT imaging will result. By placing the CT scanner in Duffield HMG will be bringing CT imaging services to a segment of the population currently more than a 30-minute drive from any CT imaging site, potentially serving a population that is currently leaving the planning district, and the state, for care. WMA's proposed CT scanner in Norton will not reach a new un-served population but will serve patients already being provided with CT imaging services at Norton Community Hospital. While the volume of scans performed at Norton Community Hospital will likely decrease, and in fact that is a stated goal of the project, the WMA project cannot be justified under the institutional need criteria of the SMFP (12VAC5-230-80), since the applicant is not an existing medical care facility that has exceeded its current service capacity.

Both requests appear to be affordable and ultimately profitable, and therefore sustainable. Both will likely have difficulty in attracting the licensed health care professionals needed to operate their respective facilities.

Staff Recommendation

<u>8669 – HMG</u>

The Division of Certificate of Public Need recommends **conditional approval** of Holston Medical Group's COPN Request number VA-8669 to establish a specialized center for CT imaging with one CT scanner in Duffield, Virginia 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. The proposed CT scanner will make CT imaging services more accessible to residents of PD 1 who currently live more than a 30-minute drive from existing.
- 3. The proposed project will provide CT imaging services to patients who are currently leaving the planning district for care.
- 4. Approval of this project is more advantageous than the alternative of the status quo.
- 5. Approval of the project would introduce the first element of institutional competition for the provision of CT imaging services in PD 1.
- 6. The capital costs are reasonable and consistent with other projects of this type.

Recommended Condition

Holston Medical Group will provide 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 0.7% of Holston Medical Group's total patient services revenue derived from CT services provided at their Duffield, Virginia facility 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. Holston Medical Group 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.

Holston Medical Group will provide 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 Holston Medical Group will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.

<u>VA-8676 – WMA</u>

The Division of Certificate of Public Need recommends **denial** of Wellmont Medical Associates' COPN Request number VA-8676 to establish a specialized center for CT imaging in Norton, Virginia with one CT scanner for the following reasons:

- 1. Based on the applicable criteria and standards of the State Medical Facilities Plan there is a need for only one additional CT scanner in PD 1, and if approved, the COPN Request number VA-8669 will fulfil that need.
- 2. The proposed project will not increase the geographic availability of CT imaging to residents living more than a 30 minutes' drive from any facility offering CT imaging.
- 3. The project further concentrates CT imaging services in the western part of PD 1.
- 4. Approval of the project reduces the opportunity for the addition of beneficial competition.