

COMMONWEALTH of VIRGINIA

Department of Health P O BOX 2448 RICHMOND, VA 23218

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

April 28, 2023

By Email

Peter M. Mellette, Esquire Mellette PC 428 McLaws Circle, Suite 200 Williamsburg, Virginia 23185

Emily W.G. Towey, Esquire Hancock Daniel 4701 Cox Road, Suite 400 Glen Allen, Virginia 23060

RE: Certificate of Public Need (COPN)
Request Numbers:

VA-8669
(COPN Number VA-04843)
Holston Medical Group, P.C. (HMG)
Duffield, Virginia, Planning District (PD) 1
Establishment of a specialized center for computed tomography (CT) imaging services with one scanner
(the "HMG project")

VA-8676
Wellmont Medical Associates, Inc. (WMA)
Norton, Virginia, PD 1
Establishment of a specialized center for
CT imaging services with one scanner
(the "WMA project")

Dear Mr. Mellette and Ms. Towey:

In accordance with Article 1.1 of Chapter 4 of Title 32.1 (§ 32.1-102.1 et seq.) of the Code of Virginia (the "COPN Law"), I have reviewed the applications captioned above. As



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required by Subsection B of Virginia Code § 32.1-102.3, I have considered all matters, listed therein, in making a determination of public need under the COPN law.

I have reviewed and adopted the enclosed findings, conclusions and recommended decision of the adjudication officer that convened the informal fact-finding conference on these applications in accordance with the Virginia Administrative Process Act, Virginia Code § 2.2-4000 et seq.

Based on my review of these applications and on the recommended decisions of the adjudication officer, I am approving the application submitted by HMG, with a condition requiring charity care, and denying the application submitted by WMA. The HMG project would meet a public need.

The reasons for my decision include the following:

- (i) The HMG project is consistent with the State Medical Facilities Plan (SMFP), is in harmony or in general agreement with the SMFP or with the public policies, interests and purposes to which the SMFP and the COPN Law are dedicated;
- (ii) The HMG project would increase geographic and financial access to CT services, while the WMA project would locate a scanner nearly adjacent to an existing hospital-based service;
- (iii) The HMG project would introduce beneficial, if modest, competition to the overall provision of diagnostic services in PD 1 and offer CT scanning at projected prices lower than the WMA project;
- (iv) The capital costs of the HMG project are highly reasonable;
- (v) The WMA project would not increase geographic access to CT services and would further concentrate CT imaging resources in the western portion of PD 1 and within the Ballad Health system; and
- (vi) This Department's Division of Certificate of Public Need (DCOPN) recommends approval of the HMG project.

Sincerely,

Parham Jaberi, MD

MARIO

Acting State Health Commissioner

Peter Mellette, Esquire Emily Towey, Esquire April 28, 2023 Page 3 of 2

Encl.

cc (via email):

Noelle Bissell, MD

Acting District Director, Lenowisco Health District

Deborah K. Waite

Virginia Health Information, Inc.

Allyson Tysinger, Esq.

Senior Assistant Attorney General

Douglas R. Harris, JD

Adjudication Officer

Erik O. Bodin, III

Director, DCOPN

MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED COMMONWEALTH OF VIRGINIA DEPARTMENT OF HEALTH

THIS CERTIFIES THAT Holston Medical Group, P.C., is authorized to initiate the proposal described herein.

NAME OF FACILITY: Duffield Imaging Center

LOCATION: 121 Advanced Tech Drive, Duffield, Virginia 24244

OWNERSHIP AND CONTROL: Holston Medical Group, P.C., will maintain ownership of and control over the approved resources.

representations made by the applicant during the course of review and adjudication. The total authorized capital cost of the project is \$762,669. The project is scheduled to be completed (as adjusted) by February 1, 2024. This Certificate is issued with the CONDITION that appears on its Reverse. SCOPE OF PROJECT: Establishment of a specialized center for computed tomography (CT) scanning, in accordance with specifications and



promulgated thereunder, this Medical Care Facilities Certificate of Public Need is issued contingent upon substantial and continuing progress towards Commissioner within twelve (12) months from the date of issuance along with adequate assurance of completion within a reasonable time period. The Pursuant to Chapter 4, Article 1:1 of Title 32.1, Sections 32.1-102.1 through 32.1-102.11, Code of Virginia (1950), as amended and the policies and procedures implementation of the proposal within twelve (12) months from the date of issuance. A progress report shall be submitted to the State Health Commissioner reserves the right 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-04843

Date of Issuance:

April 28, 2023

Expiration Date:

April 27, 2024

Acting State Health Commissioner Parham Jaberi, MD

CONDITION Placed on the Issuance of this Certificate:

shall facilitate the development and operation of primary medical care services to medically underserved persons in Planning District (PD) 1 in Holston Medical Group, P.C., shall provide CT imaging services to all persons in need of these services, regardless of their ability to pay, and an aggregate amount equal to at least 0.7% of its gross patient revenue derived from CT imaging services.

otherwise appropriately certified financial statements documenting compliance with the preceding requirement. Holston Medical Group, P.C., Compliance with this condition shall be documented to the Division of Certificate of Public Need (DCOPN) annually by providing audited or reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social individuals pursuant to this condition shall be based on the provider reimbursement methodology utilized by the Centers for Medicare and Security Act, 42 U.S.C. § 1395 et seq., which is available from Virginia Health Information, Inc. The value of charity care provided to shall accept a revised percentage based on the regional average after such time regional charity care data valued under the provider Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.

Additionally, Holston Medical Group, P.C., shall facilitate the development and operation of primary and specialty medical care services in Holston Medical Group, P.C., shall 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. designated medically underserved areas of the applicant's service area. Recommended Case Decisions Certificate of Public Need (COPN) Request Numbers:

VA-8669
Holston Medical Group, P.C.
Duffield, Virginia, Planning District (PD) 1
Establishment of a specialized center for computed tomography (CT) imaging services with one scanner

VA-8676
Wellmont Medical Associates, Inc.
Norton, Virginia, PD 1
Establishment of a specialized center for
CT imaging services with one scanner

This document contains two recommended case decisions submitted to the State Health Commissioner (hereinafter "Commissioner") for consideration and adoption. It follows a full review of the competing applications captioned above and the convening of an informal fact-finding conference (IFFC)¹ on both applications conducted in accordance with the Virginia Administrative Process Act (VAPA)² and Title 32.1 of the Code of Virginia.

Authority

Article 1 of Chapter 4 of Title 32.1 (§ 32.1-102.1 et seq.) of the Code of Virginia (the "COPN Law") addresses medical care services and provides that "[n]o person shall undertake a project described in [this Article] or regulations of the [State] Board [of Health] at or on behalf of a medical care facility . . . without first obtaining a certificate [of public need] from the Commissioner." The endeavors described and proposed in the applications fall within the statutory definition of "project" contained in the COPN Law, and, thereby, require a certificate of public need (COPN, or "Certificate") to be issued before the project may be undertaken.⁴

¹ The IFFC was held on February 1, 2023. The certified reporter's transcript of the IFFC is in the administrative record relating to this application.

² Va. Code § 2.2-4000 et seq.

³ Va. Code § 32.1-102.1:2 (A); (a "Certificate" or COPN).

⁴ Va. Code § 32.1-102.1.

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Statement of Facts

- 1. Holston Medical Group (HMG) is a for-profit Tennessee professional corporation comprising an independent, multi-specialty physician group.
- 2. The project proposed by HMG (the "HMG project") would establish a specialized center for CT services in existing space at that group's Duffield, Virginia practice location through the siting of one fixed scanner. If the HMG project were approved, HMG states it would provide additional non-COPN regulated imaging services at this center. Total capital costs of the project are \$92,000, to be defrayed using accumulated reserves.
- 3. Wellmont Medical Associates, Inc. (WMA), is a non-profit Tennessee corporation. Ballad Health is the sole member of WMA.
- 4. The project proposed by WMA (the "WMA project") would establish a specialized center for CT services, along with non-COPN regulated imaging services, through the siting of one fixed scanner across the street from Ballad Norton Community Hospital. Total capital costs of the project are \$2,485,505, to be defrayed using accumulated reserves.
- 5. On January 19, 2023, the Department of Health, Division of Certificate of Public Need (DCOPN) published a staff analysis and report recommending approval of the HMG project and denial of the WMA project (the "DCOPN Staff Report").⁵

Applications of Criteria of Public Need

The eight statutory considerations customarily applied to applications for a Certificate appear below, with discussion:

1. The extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

PD 1 currently has three CT scanners, all of which are located in hospitals along U.S. Route 58, and, as DCOPN states, are "concentrated along the western edge of the [PD]." Lower-cost, outpatient CT scanning is not available in PD 1. Both projects would be sited proximate to major highways, thereby promoting geographic access to CT services in PD 1. The HMG project would be located near the geographic center of PD 1 – the mean center of population, improving access to several localities.

⁵ DCOPN's staff report is hereby incorporated into this recommended decision by reference.

⁶ DCOPN Staff Report at 14.

⁷ HMG IFFC Exhibits 7, 9, 18, 20.

Adjudication Officer's Recommendation
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Each project would establish a specialized center, *i.e.*, a freestanding, non-hospital diagnostic imaging center for providing lower-cost CT services, thereby fostering financial access.

The HMG project involves a cost-effective 16-slice CT scanner appropriate for many patient needs. HMG states it would continue to provide patients needing more precise scanning access to 128-slice scanners at HMG's diagnostic facilities located in Tennessee.

Several localities in PD 1 have high rates of poverty. PD 1 is projected to experience a small population decline between 2020 and 2030. Much of PD 1 is mountainous, causing travel by roadway to be challenging and time-consuming.

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; (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; (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; (iv) Any costs and benefits of the project; (v) The financial accessibility of the project to the residents of the area to be served, including indigent residents; (vi) At the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a project.

DCOPN reports that that division received ten letters supporting the HMG project and six letters supporting the WMA project. WMA wrote in opposition to the HMG project, but DCOPN received no other letters opposing either project. WMA wrote in opposition to the HMG project, but DCOPN received no other letters opposing either project.

Regarding alternatives, maintaining the status quo would require patients in need of low-cost, outpatient CT scanning to undergo higher-cost scanning in an inpatient hospital in PD 1, to travel out of PD 1 or out of Virginia for scanning. Both projects involve costs and benefits, as the applicants have asserted. Both applicants appear to be committed to providing financial accessibility to patients in need.

⁸ See HMG Rebuttal at 8.

⁹ Del. T. Kilgore wrote a letter supporting each project. See also HMG IFFC Exhibit 11.

¹⁰ At the IFFC, HMG objected to WMA's opposition to its project, arguing that Ballad Health should not be permitted to oppose competition, and the HMG project in particular, due to a limitation contained in the 2017 cooperative agreement by which Ballad Health operates. The disposition of the two case decisions at hand, as recommended below, does not require a ruling on HMG's objection, which may or may not be justifiable. *See* IFFC Transcript at 76-80, HMG IFFC Exhibit 15.

3. The extent to which the proposed project is consistent with the State Health Services Plan [i.e., de facto, the SMFP]. 11

The COPN law requires that "[a]ny decision to issue . . . a [COPN] shall be consistent with the most recent applicable provisions of the [SMFP]." The SMFP, contained in the Virginia Administrative Code (VAC), includes provisions applicable to projects proposing the establishment of specialized centers for providing CT diagnostic scanning services.

A provision of the SMFP provides that CT services should be available within 30 minutes' driving time for the vast majority of a PD's population. In comparing the two projects, DCOPN observes that the HMG project would increase access to patients who are not currently within a 30-minute drive of CT services, and that the WMA project would not have such an appreciable benefit. In

Based on current utilization and the 7,400-annual-scan operational threshold in the SMFP, ¹⁵ DCOPN calculates that PD 1 has a numerical need for three scanners. Having three existing scanners, PD 1, then, has no numerical need for an additional scanner. This calculation, though, is a preliminary observation, distinct from innumerable facts and observations to be drawn in relation to seven statutory considerations, other than the one calling for deployment of the SMFP in gauging a proposed project and in making a determination of public need.

A calculation unfavorable to a project does not prevent the Commissioner from determining, in her discretion and on presentation of a sufficient case, that *one* additional scanner, to provide outpatient diagnostic services, is needed in PD 1. Public need determinations based on similar facts have been made to address rural public health needs; the advantageous siting of outpatient CT scanning is highly warranted in PD 1.

One scanner added to a PD with three existing scanners results in an incremental increase of 33.3 percent – a single-increment increase having an outsize effect as compared with that experienced in a PD with numerous scanners. Reasonably, only one of the two competing applications at hand may be approved.

WMA argues that approval of its project would help alleviate overutilization of nearby Norton Community Hospital, but this assertion is has not been substantiated or even fully established, and its assertion may be counter to prior reviews of projects recognized as proposing satisfaction of an institutional or facility-based need.¹⁶

¹¹ 12 Virginia Administrative Code (VAC) 5-230-10 et seq. While Senate Bill 764 (Acts of Assembly, c. 1271, 2020) calls for promulgation and adoption of a State Health Services Plan (SHSP) to replace the State Medical Facilities Plan (SMFP), the process for developing the SHSP has not been completed. The SMFP remains in effect as regulation in reviewing applications for a COPN.

¹² Va. Code § 32.1-102.3 (B).

^{13 12} VAC 5-230-90.

¹⁴ DCOPN Staff Report at 9.

¹⁵ 12 VAC 5-230-100.

¹⁶ The WMA project would locate a CT scanner across the street from Ballad Norton Community Hospital.

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Each of these two competing projects demonstrates adequate and general compliance with remaining applicable provisions of the SMFP and the underlying purpose of that plan.

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.

DCOPN observes that all three existing CT scanners in PD 1 are operated by acute care hospitals associated with Ballad Health, adding that "the closest Virginia CT [service] providers outside of PD 1 are also [located] in Ballad Health hospitals."¹⁷

Approval of the HMG project, then, would introduce the only CT scanner competing in PD 1 with Ballad Health. The HMG project poses little threat to CT utilization in PD 1. The only member of the corporation that is WMA is Ballad Health. The WMA project would not introduce beneficial competition, offering residents of PD 1 low-cost CT scanning.¹⁸

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.

Each project would bear an appropriate relationship to the existing health care system in the area, which is overwhelmingly operated by Ballad Health. HMG is an established physician practice group throughout the service area of Ballad Health and has an appropriate relationship with that system. The WMA project would likely decompress CT utilization at Ballad Norton Community Hospital and would also have an appropriate relationship with the existing system.

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.

Both projects are feasible. Both would financially benefit the applicants. DCOPN states that the HMG project is "among the least expensive projects" recently proposed to provide outpatient CT services. 19 Resources for construction and actual operation for each project appear generally available.

7. The extent to which the project provides improvements or innovations in the financing and delivery of health services, as demonstrated by: (i) The introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services; (ii) The potential for provision of services on an outpatient basis; (iii) Any cooperative efforts to meet regional health care needs; (iv) At the discretion of the Commissioner, any other factors as may be appropriate.

Not directly applicable, although it is notable that approval of either project would establish a low-cost, outpatient service.

¹⁷ DCOPN Staff Report at 12.

¹⁸ HMG IFFC Exhibit 10.

¹⁹ DCOPN Staff Report at 13.

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 serve (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.

Not applicable, without prejudice to either applicant.

Conclusions and Recommendation

Based on the evidence in the administrative record and the analysis that has occurred during this review, I recommend that the HMG project be approved, with a condition to ensure appropriate provision of charity care, and that the WMA project be denied.

Specific reasons supporting this recommended decision include:

- (i) The HMG project is consistent with the SMFP, is in harmony or in general agreement with the SMFP or with the public policies, interests and purposes to which the SMFP and the COPN Law are dedicated;
- (ii) The HMG project would increase geographic and financial access to CT services, while the WMA project would locate a scanner nearly adjacent to an existing hospital-based service;
- (iii) The HMG project would introduce beneficial, if modest, competition to the overall provision of diagnostic services in PD 1 and offer CT scanning at projected prices lower than the WMA project;
- (iv) The capital costs of the HMG project are highly reasonable; and
- (v) The WMA project would not increase geographic access to CT services and would further concentrate CT imaging resources in the western portion of PD 1 and within the Ballad Health system; and
- (vi) DCOPN recommends approval of the HMG project..

Respectfully submitted,

April 25, 2023

Douglas R. Harris, JD Adjudication Officer

Mohm