



COMMONWEALTH of VIRGINIA

Karen Shelton, MD
State Health Commissioner

Department of Health
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R. Christopher Lindsay
Chief Operating Officer

June 1, 2023

By Email

Stephen D. Rosenthal, Esquire
SDR Law, PLC
124 Hempstead Way
North Chesterfield, Virginia 23236

**RE: Certificate of Public Need (COPN)
No. VA-04844
(Request No. VA-8667)
James River Cardiology, P.C. (JRC)
Chesterfield, Virginia
Planning District (PD) 15
Health Planning Region IV
Establishment of a specialized center for
positron emission tomography-computed tomography
(PET-CT) services solely or cardiac purposes**

Dear Mr. Rosenthal:

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 application captioned above. As 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 the application in accordance with the Virginia Administrative Process Act, Virginia Code § 2.2-4000 *et seq.*

Based on my review of the application and on the recommended decisions of the adjudication officer, I am approving the application, with a condition addressing charity care. This project would meet a public need.

The reasons for my decision include the following:

- (i) The 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 total capital costs of the project are reasonable and include no financing costs; the project is feasible;
- (iii) Utilization levels and volume experienced by existing area providers of PET and PET/CT services is not likely to be harmed by JRC's project;
- (iv) Cardiac PET/CT reflects an important new application of technology for combatting cardiac disease and is not currently available in PD 15; and
- (v) No known opposition to JRC's project exists.

Sincerely,



Karen Shelton, MD
State Health Commissioner

Encl.: 2

cc (via email):
Alexander Samuel, MD, MPH
Director, Chesterfield 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, Division of Certificate of Public Need

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

THIS CERTIFIES THAT James River Cardiology, P.C., is authorized to initiate the proposal described herein.

NAME OF FACILITY: James River Cardiology - Chesterfield

LOCATION: 7300 Ashlake Parkway, Suite 100, Chesterfield, Virginia 23838


OWNERSHIP AND CONTROL: James River Cardiology, P.C., will maintain ownership of and control over the approved resources.

SCOPE OF PROJECT: Establishment of a specialized center for the provision of cardiac positron emission tomography-computed tomography (Cardiac PET-CT) services, *i.e.*, a combined scanning limited to cardiac diagnostic and treatment purposes, in accordance with specifications and representations made during the course of review and adjudication. The total authorized capital and financing cost of the project is \$1,001,700. The project is scheduled to be completed by November 15, 2023. The project is **CONDITIONED** to provide a derived level of charity care (see Reverse).



Pursuant to Chapter 4, Article 11 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 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 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-04844
Date of Issuance: June 1, 2023
Expiration Date: May 31, 2024


Karen Shelton, MD
State Health Commissioner

CONDITION Placed on the Issuance of this Certificate:

James River Cardiology, P.C. (below, the "certificate holder") shall provide PET/CT imaging services to all persons in need of these services, regardless of their ability to pay, and shall facilitate the development and operation of primary medical care services to medically underserved persons in Planning District (PD) 15 in an aggregate amount equal to at least **1.3%** of its **gross patient revenue** derived from PET/CT imaging services.

Compliance with this condition shall be documented to the Division of Certificate of Public Need (DCOPN) annually by the certificate holder providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement.

The certificate holder shall 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.*, which is available from Virginia Health Information, Inc. 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.*

The certificate holder shall provide the proposed 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, the certificate holder shall facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.

(Reverse)

**Recommended Case Decision
Certificate of Public Need (COPN)
Request Number VA-8667
James River Cardiology, P.C.
Chesterfield, Virginia
Planning District (PD) 15
Health Planning Region (HPR) IV
Establishment of a specialized center for
positron emission tomography-computed tomography
(PET-CT) services solely for cardiac purposes**

This document is a recommended case decision submitted to the State Health Commissioner (hereinafter, "Commissioner") for consideration and adoption. It follows full review of the record pertaining to the application captioned above, as well as the convening of an informal fact-finding conference (IFFC)¹ conducted in accordance with the Administrative Process Act² 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."³ The endeavor described and proposed in the application falls within the statutory definition of "project" contained in the COPN Law, and, thereby, requires a certificate of public need (COPN, or "Certificate") to be issued before the project may be undertaken.⁴

Statement of Facts

1. James River Cardiology, P.C. (JRC), is a professional corporation that owns and operates a specialist medical practice. It is not a subsidiary of any other entity, and it has no subsidiaries.
2. JRC provides patient care at six office sites in the central Richmond area, including an office in Colonial Heights, PD 19, and an office in Chesterfield County, PD 15.
3. On February 9, 2023, the Commissioner approved a project to establish a specialized center for cardiac PET/CT imaging at JRC's office site in Colonial Heights.⁵ This separate and

¹ The IFFC was held on March 24, 2023. A certified reporter's transcript ("Tr.") 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.

⁵ COPN No. VA-04827 (C. Greene, Commissioner).

similar application sought to, and will, serve PD 19, and areas generally to the south – an overall area distinct from PD 15, where the currently-proposed service would be located.

4. With the present application, JRC proposes to establish a specialized center for cardiac PET/CT imaging at its office site in Chesterfield County. Total capital and financing costs of the project are \$1,001,700.

Application 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.

Cardiac PET/CT has emerged to be a highly-effective means for detecting and diagnosing coronary artery disease, the leading cause of death in the U.S.⁶ While cardiac PET services are available in PD 15, the only two cardiac PET/CT services in Virginia are located outside HPR IV, specifically, in PD 5 and PD 8. While JRC has received approval for locating PET/CT services in PD 19, this site is over 30 minutes from many sites in Chesterfield County.

DCOPN observes that

[a]side from transportation time and costs, patients re reportedly choosing smaller clinics, microhospitals, freestanding [e]mergency [d]epartments, etc.[.] to meet their needs as they are easier to navigate than larger hospitals.⁷

Approval of JRC's project would place the first PET/CT scanner dedicated specifically to cardiac diagnosis in PD 15, thereby increasing residents' access to an important diagnostic tool.

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

⁶ JRC Proposed Findings and Conclusions at 11.

⁷ DCOPN Staff Report at 9.

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 received letters supporting JRC's project and no letters of opposition.

There is currently no site offering cardiac PET/CT services in PD 15. While JRC has been authorized to establish PET/CT services in PD 19, approximately 35 minutes' driving time away from its Chesterfield County office, such a distance can be expected to create hardship on residents' ability to receive certain services. Approval of the project is the only alternative that makes PET/CT services available to the growing population in PD 15, where many sophisticated, tertiary-level health care resources are already centrally located.

The costs of the project are reasonable and balanced effectively by the benefits of accessibility. JRC shows commitment to residents' financial accessibility to its services, and has agreed to the imposition of a charity care condition on issuance of a Certificate for the project.

3. The extent to which the proposed project is consistent with the State Health Services Plan [i.e., *de facto*, the SMFP].⁸

The COPN Law requires that "[a]ny decision to issue . . . a [COPN] shall be consistent with the most recent applicable provisions of the [SMFP]"⁹ The SMFP, contained in the Virginia Administrative Code (VAC), includes provisions applicable to projects proposing PET/CT services.¹⁰

A primary criterion in the SMFP the operational capacity of the technology iteration and is used to review applications for new-site PET resources, setting forth attainment of a 6000-procedure average operational level, applicable PD-wide, before approval.¹¹

Conceptually speaking, an overall, nationally-recognized, forward-looking, and data-established operational level for a scanner-based iteration of PET technology is not known or referenced in the record. Regardless, an ostensibly-reliable, evidence-based threshold might be identified, as discussed immediately below.

⁸ 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 SMFP, the process for developing the SHSP has not been completed. The SMFP remains in effect as regulation in reviewing applications for a COPN.

⁹ Va. Code § 32.1-102.3 (B).

¹⁰ 12 VAC 5-230-200 *et seq.*

¹¹ 12 VAC 5-230-210 B.

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.

One existing provider of cardiac PET scanning services in PD 15, which currently provides that scanning without benefit of concurrent CT scanning, exists in PD 15.¹⁴ It is a cardiology medical group described as being at full scanning capacity, unable to accommodate new patients,¹⁵ and serves an service area generally north of the James River. Utilization of this existing service is not likely to be harmed by approval of JRC's project.

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 DCOPN observes, the project is envisioned with the limited scope and purpose of providing only cardiac PET/CT services. JRC states, use of the scanner would be primarily intended for addressing the needs of its existing patient base.¹⁶ The project approved for locating PET/CT services at JRC's office and practice site in PD 19 is envisioned to serve an area of HPR distinct from the service area associated with the project currently under review.

The evidence overall indicates no likelihood of utilization-based harm to any existing provider of PET services or PET/CT services posed by approval of JRS's project.

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 project is feasible. The costs of the project are reasonable. JRC would partner with a known provider of PET technology and all capital expenditures would be incorporated into a turn-key lease arrangement, with monthly payments. The project would bring JRC profitable returns. Resources for construction and personnel needed for actual operation 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.

¹⁴ This existing provider has reportedly been aware of JRC's proposed project and has not written in opposition to it.

¹⁵ JRC Proposed Findings and Conclusions at 22. As well, this existing cardiac PET service reportedly plans to replace its current PET scanner (perhaps through use of the COPN Law's replacement provisions) with a PET/CT scanner due to the demonstrated advances codeployment offers. *Id.*

¹⁶ *Id.* at 23.

DCOPN observes that the project would bring vital new technology to PD 15 and HPR IV. The combination of PET scanning and CT scanning is particularly advantageous in yielding high-quality images and fewer false positives.¹⁷

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 the applicant.

Conclusions and Recommendation

Review of the record indicates sufficient evidence to support the conclusion that the project is consistent with the eight statutory considerations of public need. The project is approvable under the COPN Law. Specific reasons for this recommended decision include:

- (i) JRC's 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 total capital costs of the project are reasonable and include no financing costs; the project is feasible;
- (iii) Utilization levels and volume experienced by existing area providers of PET and PET/CT services is not likely to be harmed by JRC's project;
- (iv) Cardiac PET/CT reflects an important new application of technology for combatting cardiac disease and is not currently available in PD 15; and
- (v) No known opposition to JRC's project exists.

Respectfully submitted,



May 31, 2023

Douglas R. Harris, JD
Adjudication Officer

¹⁷ See JRC Proposed Findings and Conclusions at 24.