



COMMONWEALTH of VIRGINIA

Colin M. Greene, MD, MPH
State Health Commissioner

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September 15, 2022

By Email

Erin S. Whaley, Esquire
Troutman Pepper Hamilton Sanders LLP
1001 Haxall Point
Richmond, Virginia 23219

**Certificate of Public Need (COPN)
Request Number VA-8608
Bon Secours-St. Mary's Hospital of Richmond LLC, and
Richmond Radiation Oncology Center I LLC
Establishment of a Specialized Center for the
Provision of Radiation Therapy Services
through Relocation of One Linear Accelerator and
Introduction of One Computed Tomography (CT) Scanner
Dedicated to Radiation Treatment Simulation
Mechanicsville, Planning District (PD) 15
Health Planning Region IV**

Dear Ms. Whaley:

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

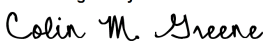
Erin S. Whaley, Esquire
September 15, 2022
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Based on my review of this application and on the recommended decision of the adjudication officer, I am denying the application. The application does not merit approval and will not receive a COPN. The project proposed in the application (the “RROC project”) is not necessary in meeting a public need.

The reasons for my decision include the following:

- (i) The RROC project is inconsistent with the State Medical Facilities Plan;
- (ii) PD 15 currently has ample radiation therapy capacity;
- (iii) The project bears clear and direct potential to harm the utilization and threaten the continued operation of an existing outpatient radiation therapy service that has capacity to meet public need;
- (iv) Opposition to the project in the marketplace, *i.e.*, opposition robustly articulated by the Virginia Commonwealth University Health System Authority, exists;
- (v) Approval of the RROC project, including both its radiation therapy component and its related CT component, would introduce directly harmful competition and would not improve access to services for residents of the area and would duplicate existing, underutilized services.

Sincerely,

DocuSigned by:

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Colin M. Greene, MD, MPH
State Health Commissioner

Encl.

cc (via email):
Tom Franck, MD, MPH
Director, Chickahominy Health District
Elaine Perry, MD, MS
Director, Richmond Health District, and Henrico 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
Division of Certificate of Public Need

Recommended Case Decision

Certificate of Public Need (COPN)

Request Number VA-8608

**Bon Secours-St. Mary's Hospital of Richmond LLC, and
Richmond Radiation Oncology Center I LLC**

**Establishment of a Specialized Center for the
Provision of Radiation Therapy Services
through Relocation of One Linear Particle Accelerator (a "linac") and
Introduction of One Computed Tomography (CT) Scanner
Dedicated to Radiation Treatment Simulation and Planning
Mechanicsville, Virginia
Health Planning Region IV
Planning District (PD) 15**

Introduction and Authority

This recommended decision is submitted to the State Health Commissioner ("Commissioner") for his consideration and adoption. It follows review of the application captioned above, including the convening of an informal fact-finding conference (IFFC)¹ on the application conducted in accordance with the Virginia Administrative Process Act (VAPA).²

Article 1 of Chapter 4 of Title 32.1 (§ 32.1-102.1 *et seq.*) of the Virginia Code ("COPN Law") addresses medical care facilities 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 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") before the endeavor may be undertaken.⁴

Factual and Procedural Background

1. Bon Secours-St. Mary's Hospital of Richmond LLC ("St. Mary's") is a Virginia limited liability company that owns and operates a 391-bed tertiary acute care hospital in Henrico County, PD 15. St. Mary's, *i.e.* the hospital, provides a comprehensive array of inpatient and outpatient services. The sole member of St. Mary's is Bon Secours-Richmond Health System, doing business as Bon Secours Virginia Health System ("Bon Secours"), which operates a health

¹ The IFFC was held in person on June 24, 2022. (The IFFC had originally been scheduled, by operation of statute, to be held on April 6, 2022, and was continued to the later date at the election of the applicants.)

² Va. Code § 2.2-4000 *et seq.*

³ Va. Code § 32.1-102.1:2 (A).

⁴ Va. Code § 32.1-102.1.

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system providing a comprehensive array of facility-based health care services at acute-care, outpatient and ambulatory sites in PD 15 and elsewhere.

2. Richmond Radiation Oncology Center I LLC (RROC) is a Virginia limited liability company and a joint venture of Accelerad, LLC and Richmond Radiation Oncology Center, Inc., the sole shareholder of which is Bon Secours-Virginia HealthSource, Inc.

3. St. Mary's and RROC (together, the "applicants") propose to establish a specialized center for radiation therapy services through the relocation of one linac from St. Mary's and the addition of one new CT scanner for treatment simulation and planning. Total capital costs of the project are \$13,083,667, to be defrayed by accumulated reserves with no financing costs.

Summary and Incorporation of Certain Text of DCOPN Staff Report

In a staff report dated March 21, 2022, prepared by the Department of Health's Division of Certificate of Public Need (DCOPN) on the RROC project (the "DCOPN staff report"), that division recommended that the Commissioner deny the project proposed by the applicants (the "RROC project"), for reasons identified therein.

By reference, the DCOPN staff report is hereby incorporated into the present recommended decision for the purpose of establishing and corroborating facts and demonstrating analysis that support and constitute the evidentiary basis on which the recommended decision made herein rests.

Analysis and Conclusions Relating to the Proposed Project

Salient analysis and conclusions regarding the RROC project and relating directly to the eight considerations of public need contained in the COPN law (the "statutory considerations"⁵ appearing in bold type), are set forth in relation to each statutory consideration below.

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

The State Medical Facilities Plan (SMFP) contains a driving time provision setting forth a normative standard that radiation therapy services should be available to the vast majority of residents within a 60 minutes. With 14 operational linacs in PD 15, one of which is operated by the Virginia Commonwealth University Health System Authority (VCU) and is located within a very short drive of, *i.e.*, less than two miles from, the site chosen by the applicants for their project, and with services generally available without distinct barriers to access, existing circumstance allows this accessibility standard to be met. Seen in this way, the RROC project would not increase access to any services in a meaningful manner. The project would not, and is not necessary to, improve access.

⁵ See Subsection B of Virginia Code § 32.1-102.3.

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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; (ii) the availability of reasonable alternatives to the proposed project that would meet the needs of people in the area to be served in a less costly, more efficient, or more effective manner; (iii) any recommendation or report of the regional health planning agency regarding an application for a certificate [*i.e.*, Certificate] that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6;⁶ (iv) any costs and benefits of the proposed project; (v) the financial accessibility of the proposed project to people in the area to be served, including indigent people; and (vi) at the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a proposed project.

DCOPN states that it received ten letters from persons associated with the applicants; all ten expressed support for the RROC project. The applicants state that community support for the RROC project is demonstrated by “more than 100 letters . . . from clinicians, patients, elected officials,⁷ community leaders, and . . . staff [of or employed by an applicant].”⁸

DCOPN received four letters of opposition from Virginia Commonwealth University Health System Authority (VCU), which noted that the project is little different from two prior projects filed by Bon Secours, one denied in 2008, the other in 2014. In these letters, VCU provided detailed discussion of how the project would harm the utilization and threaten the operation of a radiation therapy service operated by VCU, which is underutilized and located near the site envisioned by the applicants for its proposed radiation therapy service.

DCOPN identifies a viable alternative to the current project: Establishing a radiation therapy service somewhere in eastern PD 15 that is not proximate to an existing, underutilized radiation therapy service.

DCOPN finds the total capital costs of the project to be reasonable when compared to similar projects reviewed in the Commonwealth recent years. The benefits of the project include the opportunity to decompress utilization at Bon Secours Cancer Institute at Reynolds Crossing, currently operating at over 112 percent of capacity.

Regarding financial access, Bon Secours, as a health system, provides a sizeable proportion of charity care at acute care hospitals it operates in HPR IV. Bon Secours has established policies and procedures regarding charity care, and has agreed to the imposition of a condition on issuance of any Certificate that may result from these proceedings requiring an appropriately-generated level of charity care. Based on available, historical charity care data, the RROC project would likely be financially accessible to people in the area to be served, without identified barriers.

⁶ No regional health planning agency currently exists to report on projects proposed in Health Planning Region (HPR) IV, which includes PD 15.

⁷ Including a June 30, 2022, letter from S. Dunnavant, Member, Senate of Virginia.

⁸ RROC Proposed Findings and Conclusions at 2. *See* DCOPN Staff Report at 6-7.

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Of possible discretionary note, and as discussed elsewhere in this document, Bon Secours has sought to establish a specialized center for providing radiation therapy services within a short distance of Bon Secours - Memorial Regional Medical Center (MRMC), in Hanover, PD 15, since at least 2007. The Commissioner denied an application seeking approval for such a project in 2008, and a 2015 case decision of the Commissioner reaffirmed (after an IFFC) a 2014 decision that denied a request for a significant change to a separate project in PD 15, *i.e.*, one that would have, in effect, established a radiation therapy service distinctly similar to the one Bon Secours now seeks, *i.e.*, the RROC project.

Approval of either of these earlier submittals would have stood to harm the utilization and operation of the radiation therapy service already in the vicinity, indeed, on the campus of MRMC, operated by VCU. Similarly, approval of the RROC project would stand to harm that underutilized service. From a perspective of long-standing health planning and certification in Virginia, rational allocation of resources appears unlikely to be reflected now in approval of the RROC project, despite it proposing the relocation of an existing linac.

To raise an additional matter for the Commissioner's attention in exercising any discretion necessary in making a determination of public need on the RROC proposed project, approval of this project would, effectively, *remove radiation therapy services from the technological armamentarium available to patients seeking acute care and therapeutic services at St. Mary's* – a long-established, general, acute-care hospital and early provider of such services. Inpatients at St. Mary's, as well as outpatients to St. Mary's campus, would have to seek these services elsewhere.

3. The extent to which the proposed project is consistent with the State Health Services Plan [*i.e.*, *de facto*, the SMFP].⁹

The COPN law requires that “[a]ny decision to issue . . . a [COPN] shall be consistent with the most recent applicable provisions of the [SMFP]”¹⁰ The SMFP, contained in the Virginia Administrative Code (VAC), includes provisions applicable to projects involving radiation therapy services and CT services.

Under the availability provisions of the SMFP applicable to radiation therapy, “no new radiation therapy service should be approved” unless the existing linacs in a PD performed an average of 8,000 treatments annually.¹¹ DCOPN maintains that the RROC project would establish a new service, despite the project involving a relocation of an existing linac, concluding that this SMFP provisions applies to the RROC project. In 2020, the linacs in PD 15 operated at 62.8 percent of this threshold, although the applicants suggest the actual level, based on 2019

⁹ 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. Therefore, the SMFP remains in effect as regulatory guidance in reviewing applications for a COPN.

¹⁰ Va. Code § 32.1-102.3 (B).

¹¹ 12 VAC 5-230-290 (A).

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data, is over 72 percent. This provision and the prevailing operational level indicate no need for a new radiation therapy service in PD 15.¹²

The applicants, observing that the RROC project involves relocation and is inventory neutral, argue that the 8,000-procedure provision is inapplicable to the project, so the low average operation of PD 15 linacs is not relevant to the analysis needed in this review. I disagree with RROC's contention. Although the RROC project would not add a linac to the inventory of linacs in PD 15, it would be, in the admitting phrasing of the applicants, an "establishment of a new medical care facility,"¹³ and thereby, it would constitute a new radiation therapy service to which the availability provisions of the SMFP apply.

This availability provisions of the SMFP also advises that a new radiation therapy service should not be approved unless it will perform at least 5,000 procedures by the second year of operation without reducing the utilization of existing service providers. The applicants anticipate that the proposed service will provide 6,065 procedures in its second year and that this level of utilization is based "solely on patients that [the applicants are] currently treating [at their various sites in PD 15]."¹⁴ The applicants' utilization projection is optimistic, and, if attained, is likely to harm utilization at VCU's radiation therapy service, which has a primary service area that largely overlaps that prepared by the applicants for the RROC project.

In addition, by operation of a computational methodology contained in the availability provisions of the SMFP,¹⁵ PD 15 has a projected, calculated 2025 *surplus* of five linacs, according to DCOPN. The applicants, and apparently VCU (which is keenly interested in this case), contend the surplus is only three. Regardless, the computational methodology indicates no need for a new radiation therapy service in PD 15. The RROC project is inconsistent with the availability provisions in the SMFP.¹⁶

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.

Since the service that would result from approval of the RROC project is highly likely to reduce appreciably the utilization of the radiation therapy service operated nearby by VCU on the campus of MRMC, any competition introduced by the project would not be beneficial competition. The area to be served would not be benefitted by approval of the RROC project.

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.

¹² See DCOPN Staff Report pp. 9-18.

¹³ RROC Proposed Findings and Conclusions (Appendix A) at 33.

¹⁴ *Id.* at 32.

¹⁵ See 12 VAC 5-230-290 (B).

¹⁶ The RROC project includes a CT scanner to assist with treatment planning and overall operation of the proposed radiation therapy service. Since analysis of the project under the SMFP provisions governing radiation therapy is dispositive and a CT scanner would not be necessary but for establishment of the proposed radiation therapy service, discussion of the CT portion of the project is omitted here and the DCOPN staff report should be consulted for relevant discussion.

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The RROC project would harm the utilization and threaten the sustainability of an existing radiation therapy service, specifically, the service established several years ago and continually operated by VCU on the campus of MRMC. VCU's service, specifically, a service site of Massey Cancer Center, is underutilized and has existing capacity to meet public need.¹⁷

The applicants argue that the project would not divert patients from VCU's service because referral patterns are defined, aligned with the health systems and unlikely to change. This argument appears specious, as physicians associated with MRMC, a hospital within the healthcare system that is Bon Secours, could increasingly find it appropriate to begin referring patients to the radiation therapy service proposed by the applicants, which would also be within Bon Secours.

The relationship of the proposed project to the existing health care system of the area, therefore, would not be a positive one.

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.

DCOPN concludes that the RROC project is feasible with regard to financial costs in both the immediate and the long term. The project would be financially beneficial to the applicants, the costs of construction appear reasonable, and financial and human resources appear to be available. The cost of capital, as that matter is conventionally understood under this statutory consideration, does not appear to present an issue.

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.

In relation to the second subitem of this statutory consideration, the RROC project would provide, and promote the provision of, services on an outpatient basis. The remaining subitems are inapplicable to the project.

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

¹⁷ In commenting in writing on this application, VCU asserts that radiation therapy service treatment patient volumes are "declining in part because of evolving best practices for radiation therapy treatment plans," resulting in a general trend toward less frequent, higher dose treatment visits for cancer patients. Ltr. A. Kellermann to N. Megibow, Feb. 11, 2022 at 8.

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This statutory consideration is not applicable to the RROC project. Notably, however, approval of the project would likely bear direct harm to the utilization and sustainability of the radiation therapy service currently operated by VCU, a teaching hospital associated with a medical school located in PD 15.

Conclusion and Recommendation

In light of all eight statutory considerations and upon review of the administrative record compiled in relation to the RROC project, I conclude that the project would fail to meet a public need and does not merits approval. I recommend that the RROC project be denied, as it is not necessary to meet a public need.

Specific reasons supporting this recommendation include:

- (i) The RROC project is inconsistent with the SMFP;
- (ii) PD 15 currently has ample radiation therapy capacity;
- (iii) The project bears clear and direct potential to harm the utilization and threaten the continued operation of an existing outpatient radiation therapy service that has capacity to meet public need;
- (iv) Opposition to the project in the marketplace, *i.e.*, opposition robustly articulated by VCU, exists;
- (v) Approval of the RROC project, including both its radiation therapy component and its related CT component, would introduce directly harmful competition and would not improve access to services for residents of the area and would duplicate existing, underutilized services.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read "D. Harris", with a stylized flourish at the end.

September 12, 2022

Douglas R. Harris, JD
Adjudication Officer