



COMMONWEALTH of VIRGINIA

Karen Shelton, MD
State Health Commissioner

Department of Health
P O BOX 2448
RICHMOND, VA 23218

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

October 13, 2023

Ms. Kathie Riebling
6160 Kempsville Circle
Suite 250-B
Norfolk, Virginia 23502

**RE: COPN No. VA-04860
Excellence ASC, LLC, Norfolk, Virginia
Introduce Radiation Therapy for Ocular Oncology**

Dear Ms. Riebling:

In accordance with Chapter 4, Article 1.1 of Title 32.1 of the Code of Virginia of 1950 (the Code), as amended, I reviewed the application and all supporting documents submitted by Excellence ASC, LLC to introduce radiation therapy for ocular oncology.

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

1. The 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. Radiation therapy for ocular oncology is offered at only one other provider in the Commonwealth, and that provider is approximately 200 miles from the location of the proposed project.
3. There are no providers of brachytherapy for ocular tumors in PD 20.
4. A reasonable, less costly, more efficient alternative to the proposed project does not exist, and the proposed project is more advantageous than maintaining the status quo.
5. There is no known opposition to the project.

Ms. Kathie Riebling
Excellence ASC, LLC
October 13, 2023
Page 2

This certificate is valid for the period October 13, 2023, through October 12, 2024.
The total authorized capital cost of the project is \$6,650.00.

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

Sincerely,



Karen Shelton, MD
State Health Commissioner

Enclosure

cc: Allyson Tysinger, Senior Assistant Attorney General, Commonwealth of Virginia
Erik Bodin, Director, Division of Certificate of Public Need
Deborah K. Waite, Chief Operating Officer, Virginia Health Information
Susan Girois, MD, MPH, District Director, Norfolk Health District

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

THIS CERTIFIES THAT Excellence ASC, LLC is authorized to initiate the proposal as described below.

NAME OF FACILITY: Excellence ASC, LLC

LOCATION: 863 Glenrock Road, Norfolk, Virginia 23502

OWNERSHIP AND CONTROL: Excellence ASC, LLC

SCOPE OF PROJECT: Introduce radiation therapy for ocular oncology. Capital costs authorized for this project total \$6,650.00. The project is expected to be completed by May 31, 2024. This certificate is issued with the condition that appears on its reverse.



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

Certificate Number: VA-04860

Date of Issuance: October 13, 2023

Expiration Date: October 12, 2024

Karen Shelton, MD, State Health Commissioner

Excellence ASC, LLC will provide radiation therapy 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 6.0% of Excellence ASC, LLC's total patient services revenue derived from radiation therapy services 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. Excellence ASC, LLC will accept a revised percentage based on the regional average after such time regional charity care data valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. is available from Virginia Health Information. The value of charity care provided 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.

Excellence ASC, LLC will provide radiation therapy 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 Excellence ASC, LLC will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis Report

September 18, 2023

COPN Request No. VA-8694

Excellence ASC, LLC

Norfolk, Virginia

Introduce Radiation Therapy for Ocular Oncology

Applicant

Excellence ASC, LLC (EASC) is a limited liability company formed in 2021 under the laws of the Commonwealth of Virginia. EASC will be located in Norfolk, Virginia, which is in Planning District (PD) 20, Health Planning Region (HPR) V.

Background

The State Medical Facilities Plan (SMFP) defines radiation therapy as “treatment using ionizing radiation to destroy diseased cells and for the relief of symptoms. Radiation therapy may be used alone or in combination with surgery or chemotherapy.”¹ Additionally, the American College of Radiology describes brachytherapy as “a radiotherapeutic method in which radionuclide or electronic sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.”²

According to Virginia Health Information (VHI) data and Division of Certificate of Public Need (DCOPN) records, there are seven providers of radiation therapy in PD 20, including six providers of brachytherapy (**Table 1**).

¹ 12 VAC5-230-10

² American College of Radiology. ACR.org. Accessed September 6, 2023. ACR–ABS–ASTRO Practice Parameter For The Performance of Radionuclide-based High-Dose-Rate Brachytherapy. <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/hdr-brachyro.pdf?la=en>

Table 1. COPN Authorized Radiation Therapy Providers in PD 20

Facility	Linear Accelerators	Brachytherapy
Bon Secours Cancer Institute at Harbour View	2*	1
Chesapeake Regional Medical Center	2	1
Sentara Norfolk General Hospital	2	1
Sentara Obici Hospital	1	1
Sentara Virginia Beach General Hospital	1	1
Virginia Oncology Associates - Princess Anne	1	0
Sentara Brock Cancer Center	2	1
Total	11	6

Source: VHI (2021) and DCOPN Records

*COPN No. VA-04839, dated April 11, 2023 authorized Maryview Hospital, LLC d/b/a Bon Secours Maryview Medical Center to add one SRS capable linear accelerator by relocation from Maryview's Norfolk Campus (formerly Bon Secours DePaul Medical Center). The project is expected to be completed May 2025.

The owners of EASC, Dr. Alan L. Wagner and Dr. Kapil G. Kapoor, currently provide ophthalmic services at Wagner Macola & Retina Center (WMRC). WMRC has served Hampton Roads, the eastern portion of North Carolina and southern Maryland for over 30 years. WMRC currently provides a wide array of ophthalmic services, education, public health outreach with health screening, and specializes in diabetic retinopathy, macular degeneration, eye tumors, and the diagnosis and management of complex medical and surgical eye disease.

Pursuant to COPN No. VA-04812, dated October 7, 2022, the State Health Commissioner (Commissioner) authorized EASC to establish an outpatient surgical hospital (OSH) with two operating rooms dedicated to and limited to ophthalmic surgery. The OSH is scheduled to be completed by October 1, 2023. In addition to the COPN-authorized ophthalmic surgical services, the applicant proposes to introduce radiation therapy services to treat ocular tumors in the form of premade custom-prepared small pieces of gold that are preloaded with tiny radioactive seeds called a plaque.

According to the applicant “[n]o Virginian has access to ocular oncology surgical care anywhere in Virginia...” and “[a]n OR for ocular oncology surgery requires special equipment and specialty staff. There was only [one] facility in Virginia that had an OR equipped for ocular oncology surgery - Bon Secours DePaul Medical Center. DePaul closed in 2021 and there is now no facility in Virginia, much less in PD 20, equipped for ocular oncology surgery, and those patients have to be referred to Wills Eye Hospital in Philadelphia, Memorial Slone Kettering in New York City, Duke University Hospital in North Carolina, or to facilities even farther North or West....” and “Drs. Wagner and Kapoor, the principals of the Applicant, are the only [two] ocular oncologists in the vast majority of Virginia....” and “[o]ver the last [six] years, WMRC has approached health care facilities in PD 20 and asked them to implement an oncology program and install ocular oncology equipment. The facilities have rejected the requests.”³

³ Application for COPN Request No. VA-8694.

DCOPN notes that since the May 31, 2023 submission of the application for COPN Request No. VA-8694, Augusta Health has reported:

[In July, 2023], EyeOne ophthalmologist Eugene Shildkrot, MD, Director of Ocular Oncology Services, performed the first eye plaque surgeries at Augusta Health. “This was a historic day for our community, says Scott Crabtree, Vice President of Augusta Health Professional Services. “We can now provide this highly specialized eye cancer procedure here at Augusta Health for the patients in our community and surrounding regions.”⁴

DCOPN also notes that Augusta Health is located in Fishersville, Virginia, approximately 200 miles northwest of the location of the proposed project. Augusta Health is located in PD 6, HPR I.

Proposed Project

In addition to the COPN authorized two operating room OSH for ophthalmic surgical services, the applicant proposes to introduce radiation therapy services in the form of premade custom-prepared small pieces of gold that are preloaded with tiny radioactive seeds (plaque). According to the applicant, the plaque will be stored offsite, and a physicist will bring the plaque to EASC in a radioprotective box the day of the surgery. The surgeons suture the plaque to the wall of the eye, adjacent to the tumor. Post-surgery, the patient is discharged, and the plaque is left in place for several days until the required dose of radiation has been delivered, after which the patient returns to EASC to have the plaque removed.

The total capital and financing costs of the proposed project are \$6,650, which represent the costs for the construction of the hot lab, signage and a locking door and cabinet. (Table 2). The applicant will fund the project using its accumulated reserves. Accordingly, there are no financing costs associated with this project.

Table 2. EASC Capital and Financing Costs

Direct Construction Costs	\$5,000.00
Equipment Not Included in Construction Contract	\$1,650.00
Total	\$6,650.00

Source: COPN Request No. VA-8694

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the “[i]ntroduction into an existing medical care facility described in subsection A any...radiation therapy....” A medical care facility is defined, in part, as “[a]ny facility licensed as a hospital, as defined in § 32.1-123.”

⁴ Augusta Health. AugustaHealth.com *An Eye-Saving Treatment for Melanoma in the Eye*. Accessed September 6, 2023. <https://www.augustahealth.com/2023/07/an-eye-saving-treatment-for-melanoma-in-the-eye/>

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

Pursuant to Section 32.1-102.3 of the Code of Virginia, in determining whether a public need for a project exists, the following factors shall be considered:

- 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;**

Geographically, EASC will be located at 863 Glenrock Road, Norfolk, Virginia and is accessible via Route 13, Route 58, Interstate 64 and Interstate 264. Furthermore, EASC will be located at a major regional intersection of public bus and light rail transportation and there is a Hampton Roads Transit bus stop directly across the street.

As depicted in **Table 3**, at an average annual growth rate of 0.52%, PD 20's population growth rate is slightly below the state's average annual growth rate of 0.77%. Overall, the planning district is projected to add an estimated 62,104 people in the 10-year period ending in 2020 – an average increase of 6,210 people annually and 47,742 in the 10-year period ending 2030 – an average increase of 4,774 people annually.

Regarding the 65+ age group for PD 20, Weldon-Cooper projects a more rapid increase in population growth (an approximate 35% increase from 2010 to 2020 and approximately 33% from 2020 to 2030). Weldon-Cooper further projects that statewide, the 65+ age cohort population will increase at a rate of approximately 38% from 2010 to 2030 and approximately 27% from 2020 to 2030.

Table 3. Population Projections for PD 20, 2010-2030

Locality	2010	2020	% Change 2010-2020	Avg Ann % Change 2010-2020	2030	% Change 2020-2030	Avg Ann % Change 2020-2030
Isle of Wight	35,270	38,060	7.91%	0.75%	41,823	9.89%	0.95%
Southampton	18,570	17,739	-4.47%	-0.45%	17,711	-0.16%	-0.02%
Chesapeake	222,209	249,244	12.17%	1.13%	270,506	8.53%	0.82%
Franklin	8,582	8,268	-3.66%	-0.36%	8,140	-1.55%	-0.16%
Norfolk	242,803	246,881	1.68%	0.16%	249,889	1.22%	0.12%
Portsmouth	95,535	95,027	-0.53%	-0.05%	90,715	-4.54%	-0.46%
Suffolk	84,585	94,733	12.00%	1.11%	109,424	15.51%	1.45%
Virginia Beach	437,994	457,699	4.50%	0.43%	467,187	2.07%	0.21%
Total PD 20	1,145,548	1,207,652	5.42%	0.52%	1,255,394	3.95%	0.39%
PD 20 65+	124,196	167,891	35.18%	2.98%	222,845	32.73%	2.87%
Virginia	8,001,024	8,655,021	8.17%	0.77%	9,331,666	7.82%	0.76%
Virginia 65+	976,937	1,352,448	38.44%	3.22%	1,723,382	27.43%	2.45%

Source: U.S. Census, Weldon Cooper Center Projections (June 2019) and DCOPN (interpolations)

Regarding socioeconomic barriers to access to the applicant's services, according to regional and statewide data regularly collected by VHI, for 2021, the most recent year for which such data is available, the average amount of charity care provided by HPR V facilities was 2.15% of all reported total gross patient revenues (**Table 4**). Pursuant to § 32.1-102.4B of the Code of Virginia DCOPN must now place a charity care condition on every applicant seeking a COPN. Should the Commissioner approve the proposed project, the applicant has proffered a charity care condition of 6% of gross patient revenue. Accordingly, DCOPN recommends a charity care condition of 6%, in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

Table 4. HPR V Charity Care Contributions: 2021

Charity Care Contributions at or below 200% of Federal Poverty Level			
Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Shore Memorial Hospital	\$269,907,727	\$9,422,924	3.49%
Sentara Careplex Hospital	\$1,017,574,248	\$34,066,691	3.35%
Sentara Norfolk General Hospital	\$4,140,257,319	\$128,762,704	3.11%
Riverside Doctors' Hospital Williamsburg	\$ 179,426,271	\$5,432,225	3.03%
VCU Health Tappahannock Hospital	\$92,960,711	\$2,700,950	2.91%
Sentara Obici Hospital	\$1,087,729,489	\$30,962,016	2.85%
Riverside Walter Reed Hospital	\$ 287,948,364	\$7,863,937	2.73%
Chesapeake General Hospital	\$1,072,529,357	\$27,311,983	2.55%
Select Specialty Hospital-Hampton Roads	\$52,682,414	\$1,306,102	2.48%
Sentara Virginia Beach General Hospital	\$1,498,811,465	\$32,606,150	2.18%
Sentara Leigh Hospital	\$1,693,550,753	\$35,862,784	2.12%
Riverside Regional Medical Center	\$2,520,629,397	\$50,712,093	2.01%
Newport News Behavioral Health Center	\$34,327,936	\$674,329	1.96%
Sentara Princess Anne Hospital	\$1,211,917,351	\$20,507,610	1.69%
Sentara Williamsburg Regional Medical Center	\$730,844,393	\$11,014,243	1.51%
Rappahannock General Hospital	\$84,262,971	\$1,208,624	1.43%
Southampton Medical Center	\$202,382,082	\$2,878,626	1.42%
Bon Secours Mary Immaculate Hospital	\$695,764,105	\$4,616,676	0.66%
Bon Secours Maryview Medical Center	\$1,277,812,385	\$7,962,270	0.62%
Riverside Rehabilitation Hospital	\$48,989,384	\$248,297	0.51%
Virginia Beach Psychiatric Center	\$53,896,135	\$261,760	0.49%
Children's Hospital of the King's Daughters	\$1,148,982,976	\$3,770,291	0.33%
Hospital For Extended Recovery	\$29,149,289	\$68,918	0.24%
Kempsville Center for Behavioral Health	\$45,848,943	\$0	0.00%
Lake Taylor Transitional Care Hospital	\$46,260,612	\$0	0.00%
Total Facilities Reporting			25
Median			2.0%
Total \$ & Mean %	\$19,524,446,077	\$420,222,203	2.15%

Source: VHI (2021)

DCOPN is not aware of any other distinct and unique geographic, socioeconomic, cultural, transportation, or other barriers to care that this project would address.

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;

DCOPN received 21 letters of support for the proposed project from members of the local medical community, former patients of the applicant and members of Virginia government, which addressed:

- WMRC is a leader in innovative research treatments and the only provider of ocular oncology treatment for the entire region.
- Drs. Wagner and Kapoor no longer have access to treat patients with eye tumors after the closure of Bon Secours DePaul Hospital.
- Requiring patients to travel out of state for ocular oncology treatment increases their treatment burden, cost of care and patient satisfaction.
- Patients should be able to receive care when they need it, and they shouldn't have to leave Virginia to do so.
- EASC will help bridge the gap in available healthcare solutions and impact the community.
- WMRC has been generous in providing free eye care to those in need but is limited by availability of treatment and surgery space.
- Drs. Wagner and Kapoor have consistently provided care to underserved and needy communities in their region.

DCOPN did not receive any letters in opposition to the proposed project.

Public Hearing

DCOPN provided notice to the public regarding this project on July 10, 2023. The public comment period closed on August 24, 2023. Section 32.1-102.6 B of the Code of Virginia directs DCOPN to hold one public hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city in the case of competing applications; or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. COPN Request No. VA-8694 is not competing with another project in this batch cycle and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing was held.

(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;

With regard to access to treatment for ocular oncology, the applicant explains that “patients have to be referred to Wills Eye Hospital in Philadelphia, Memorial Sloane Kettering in New York City, Duke University Hospital in North Carolina, or to facilities even farther North or West.” DCOPN notes that since the May 31, 2023 submission of the application for COPN Request No. VA-8694, Augusta Health has reported that it has performed “the first eye plaque surgeries at Augusta Health.”⁵ DCOPN notes the distances to these providers from the location of the proposed project below⁶:

- Memorial Sloane Kettering – 367 miles, 6 hours, 37 minutes;
- Will Eye Hospital – 272 miles, 4 hours, 59 minutes;
- Duke University Hospital – 192 miles, 3 hours, 23 minutes; and
- Augusta Health – 195 miles, 3 hours, 14 minutes

In the Informal Fact-Finding Conference (IFFC) for COPN Request No. VA-8580, the applicant’s proposal to establish an OSH with two operating rooms limited to vitreoretinal and ophthalmic surgery, the applicant outlined the difficulties faced by patients requiring treatment for ocular cancer. Dr. Kapoor explained:

...that’s a huge toll on patients to know that you have a potentially blinding and a potentially life-threatening condition. And you are now going to set up for at least three visits out of the state. One for the first evaluation, because you don’t just go up and have surgery. And then you schedule and come back for surgery. And then you’ll have a second surgery to get the implant out. And then at least one post-op visit. And depending on the state, some of these patients are staying in the hospital while they’re there because of state regulations or they’re staying in a hotel. So for example, Wills Eye Hospital says you have to stay at the hotel within one mile of the hospital at all times while you have a radioactive implant. And that’s a regulation....Four days. While the implant is there, you’ve got to get there the night before and stay until the day, so they vary.⁷

DCOPN is not aware of any reasonable alternatives to the proposed project. Under the status quo, patients requiring treatment for ocular tumors will continue to have to travel great distances for treatment, experiencing the challenges outlined by the applicant. Furthermore, DCOPN notes that brachytherapy for ocular tumors is offered at only one other provider in the Commonwealth, and that provider is approximately 200 miles from the location of the proposed project. There are no providers of brachytherapy for ocular tumors in PD 20. DCOPN also notes that the

⁵ Augusta Health. AugustaHealth.com *An Eye-Saving Treatment for Melanoma in the Eye*. Accessed September 6, 2023. <https://www.augustahealth.com/2023/07/an-eye-saving-treatment-for-melanoma-in-the-eye/>

⁶ Distances per Google maps, accessed September 8, 2023.

⁷ COPN Request No. VA-8580, IFFC transcript at 114-22.

applicant will incur very minimal capital costs to operationalize the proposed project and no additional staffing is needed for the proposed project.

For these reasons, DCOPN finds that the proposed project to introduce radiation oncology for ocular oncology is more advantageous than maintaining the status quo.

(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 V designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 20. Therefore, this consideration is not applicable to the review of the proposed project.

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

As shown in **Table 2**, the estimated capital costs of the proposed project are \$6,650, which represent the costs for the construction of the hot lab, signage and a locking door and cabinet. The applicant will fund the project using its accumulated reserves. Accordingly, there are no financing costs associated with this project. DCOPN concludes that these costs are modest and will be easily covered by the applicant.

The applicant identified numerous benefits to the proposed project, including:

- This project will be the only radiation therapy service for treating intraocular tumors in Virginia, promoting both the availability and accessibility of a service that does not now exist.⁸
- As evidenced by COPN No. VA-04812, EASC has committed to providing charity care of 6% of gross patient revenue, eclipsing all other providers (both hospitals and ASCs) in Planning District 20. Excellence ASC is committed to providing services to every person who needs them without respect to a person's ability to pay.
- This project will introduce the latest technology for the treatment of eye cancer and, together with the already approved COPN No. VA-04812, will introduce into the planning district the most current surgical procedures for eye diseases, including surgical implants of the recently FDA-approved treatment for "wet" age-related macular degeneration, a disease that impacts approximately 20 million people worldwide and is a leading cause of blindness in people over the age of 60.
- All EASC services will be on an outpatient basis and will be a lower cost alternative to area hospitals.

⁸ DCOPN notes that since the May 31, 2023 submission of the application for COPN Request No. VA-8694, Augusta Health has reported it has performed brachytherapy for ocular oncology.

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

According to the applicant:

Prior to DePaul's closing, WMRC physicians would provide free care to needy patients and DePaul would substantially discount its fees for those patients, making eye surgeries accessible to indigent people. Post DePaul closing, however, even though WMRC still provides free care, the existing hospitals and ASCs do not offer the generous charity care that DePaul did, and many needy patients are forced to forego treatment. While WMRC can offer free services, it obviously cannot control the charity care policies of the facilities at which its physicians operate. Even if it could, there is now no facility equipped for eye tumor surgery. It will, however, control the charity care policies of Excellence ASC, which will continue to provide free and reduced-cost care, expanding financial accessibility to those in need.

The Pro Forma Income Statement provided by the applicant includes the provision of charity care in the amount of 6% (Table 5). As previously discussed, recent changes to § 32.1-102.4B of the Code of Virginia now require DCOPN to place a charity care condition on every applicant seeking a COPN. DCOPN recommends that, if approved, the proposed project should be subject to a charity care condition of 6%, as proffered by the applicant, in addition to any new requirements as found in the revised § 32.1-102.4B of the Code of Virginia.

Table 5. EASC Pro Forma Income Statement

	Year 1	Year 2
Projected Volume	90	100
Gross Patient Revenue	\$450,000	\$550,000
Contractual Adjustments	(\$245,000)	(\$295,000)
Charity	(\$27,000)	(\$33,000)
Net Patient Services Revenue	\$178,000	\$222,000
Total Operating Expenses	\$87,520	\$95,960
Net Income	\$90,480	\$126,040

Source: COPN Request No. VA-8694

- (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 notes that Bon Secours – DePaul Medial Center (DePaul) in Norfolk, Virginia ceased operation as an acute care hospital and surrendered its hospital license on April 1, 2021. Prior to the closure, DePaul operated two linear accelerators and also offered brachytherapy services.

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 SMFP. They are as follows:

The SMFP contains criteria/standards for radiation therapy services. They are as follows:

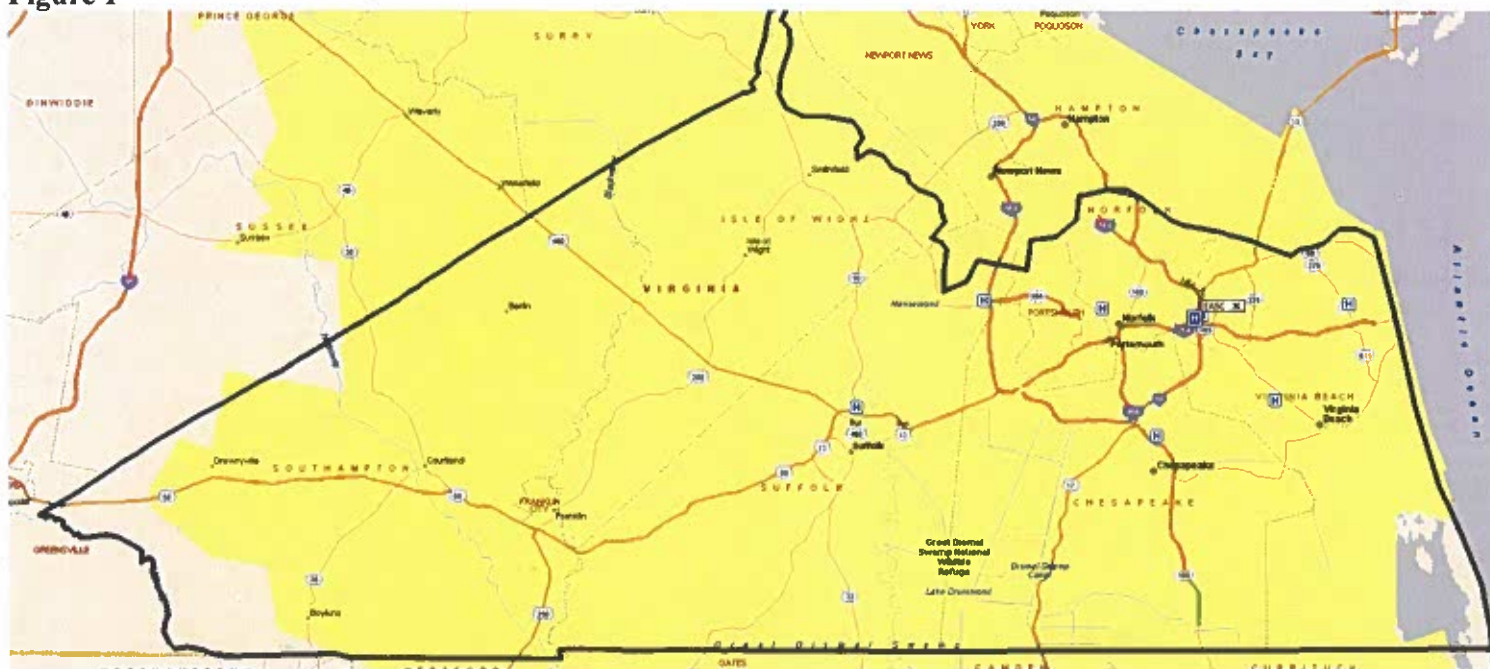
Part III
Radiation Therapy Services
Criteria and Standards for Radiation Therapy Services

12VAC5-230-280. Travel time.

Radiation therapy services should be available within 60 minutes driving time one way under normal conditions of 95% of the population of the health planning district using a mapping software as determined by the commissioner.

The heavy black line in **Figure 1** shows the boundary of PD 20. The white “H” symbols mark the locations of existing radiation therapy providers in PD 20. The blue “H” symbol marks the location of the proposed project. The yellow shading illustrates the area that is within a 60-minute driving time of the existing radiation therapy providers in PD 20. Based on the shaded area in **Figure 1**, it is reasonable to conclude that 95% of the population of PD 20 is within 60 minutes driving-time one-way under normal traffic conditions of radiation therapy services. While DCOPN observes that the SMFP standard as outlined in 12VAC5-230-280 is satisfied with regard to radiation therapy, it notes that the unique service proposed by the applicant is offered at only one other provider in the Commonwealth; and that provider is approximately 200 miles from the location of the proposed project. There is no provider of the brachytherapy for ocular oncology in PD 20.

Figure 1



12VAC5-230-290. Need for new service.

A. No new radiation therapy service should be approved unless:

1. Existing radiation therapy machines located in the health planning district performed an average of 8,000 procedures per existing and approved radiation therapy machine in the relevant reporting period; and
2. The new service will perform at least 5,000 procedures by the second year of operation without significantly reducing the utilization of existing providers in the health planning district.

As previously discussed, the applicant is not seeking to add a new radiation therapy machine, but instead is seeking to add ocular oncology focused radiation therapy, which is not currently offered in PD 20.

B. The number of radiation therapy machines needed in a health planning district will be determined as follows:

$$\frac{\text{Population} \times \text{Cancer Incidence Rate} \times 60\%}{320}$$

where:

1. The population is projected to be at least 150,000 people three years from the current year as reported in the most current projections of a demographic entity as determined by the commissioner;
2. The cancer incidence rate as determined by data from the Statewide Cancer Registry;
3. 60% is the estimated number of new cancer cases in a health planning district that are treatable with radiation therapy; and
4. 320 is 100% utilization of a radiation therapy machine based upon an anticipated average of 25 procedures per case.

As previously discussed, the applicant is not seeking to add a new radiation therapy machine, but instead is seeking to add ocular oncology focused radiation therapy, which is not currently offered in PD 20.

C. Proposals for new radiation therapy services located less than 60 minutes driving time one way, under normal conditions, from any site that radiation therapy services are available shall demonstrate that the proposed new services will perform an average of 4,500 procedures annually by the second year of operation, without significantly reducing the utilization of existing services in the health planning district.

As shown in Table 5, the applicant anticipates performing 90 procedures in year one and 100 procedures in year two. As previously discussed, the applicant is not seeking to add a new radiation therapy machine, but instead is seeking to add ocular oncology focused radiation therapy. Furthermore, the unique service is offered at only one other provider in the Commonwealth, and that provider is approximately 200 miles from the location of the proposed project. There are no providers of brachytherapy for ocular tumors in PD 20. Thus, there will be no effect on the utilization of existing services.

12VAC5-230-300. Expansion of service.

Proposals to expand radiation therapy services should be approved only when all existing radiation therapy services operated by the applicant in the health planning district have performed an average of 8,000 procedures for the relevant reporting period and the proposed expansion would not significantly reduce the utilization of existing providers.

Not applicable. The proposed project does not involve an expansion of a radiation therapy service.

12VAC5-230-310. Statewide Cancer Registry.

Facilities with radiation therapy services shall participate in the Statewide Cancer Registry as required by Article 9 (§ 32.1-70 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia

The applicant has provided assurances that EASC will participate in the Statewide Cancer Registry as required by Article 9 (§ 32.1-70 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia.

12VAC5-230-320. Staffing.

Radiation therapy services should be under the direction or supervision of one or more qualified physicians designated or authorized by the Nuclear Regulatory Commission or the Division of Radiologic Health of the Virginia Department of Health, as applicable.

The applicant has provided assurances that its radiation therapy services will be under the direction or supervision of Board-certified physicians designated or authorized by the Nuclear Regulatory Commission or the Division of Radiologic Health of the Virginia Department of Health, as applicable.

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;**

As there are no providers of radiation therapy for ocular oncology in PD 20, the proposed project would foster institutional competition and will improve access to essential health care services for all people in the area to be served. Regarding this consideration, the applicant provided the following information:

For many years, WMRC has tried to get outpatient facilities and hospital systems in PD 20 to add ocular oncological equipment to their operating rooms but has had no success. The addition of this equipment that is now non-existent in the Planning District will likely spur beneficial competition with other providers. Additionally, as an outpatient surgical facility, Excellence ASC will provide residents of PD 20 with an alternative means of receiving ophthalmic surgical services at a lower cost than at area hospitals, which will foster institutional competition to the benefit of all people in PD 20.

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;

There are no providers of brachytherapy for ocular tumors in PD 20. Thus, there will be no effect on the utilization of existing services.

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;

As already discussed, DCOPN contends that the projected costs of \$6,650 are modest. The entirety of the capital costs will be funded using the accumulated reserves of the applicant. Accordingly, there are no financing costs associated with this project. The Pro Forma Income Statement provided by the applicant projects a net profit of \$90,480 from in the first year of operation, and a net profit of \$126,040 in the second year of operation.

The applicant contends that no additional staffing is needed for the proposed project and that the staffing approved pursuant to COPN No. VA-04812 included the staffing needed for the radiation oncology program. For purposes of completeness, in the applicant for COPN No. VA-04812, the applicant lists a need for:

- 2 Administrative Professionals
- 5.5 Registered Nurses; and
- 3.5 Surgical Technicians.

With regard to its recruitment practices, the applicant asserts:

WMRC possesses a robust and decades' old successful human resources department that will be used at start-up to provide and train staffing needs.

WMRC believes it is important to provide a staff of committed, trained medical professionals. It will advertise for, recruit and interview carefully applicants who wish to work in the ASC. The Director of Nursing will be hired at least five months prior to the opening of the ASC, allowing him/her the time needed to find and hire appropriate qualified persons prior to the opening of the facility. As needed, the ASC may use PRN staff to supplement the full-time staff in the center. Many medical professionals are available who need some accommodations for family responsibilities and these people find part time work helpful to their particular situations.

As active teaching faculty at two medical schools, the owners of the ASC have decades of documented world class experience and dedication to the delivery of ongoing professional education to colleagues and staff for skills improvement and promotion of a safe work environment. In addition, they believe it is important for the ASC to commit to its employees and to an exceptional and positive workplace. In doing so, Excellence ASC will foster committed employees who wish to work in the center. Many employees will find the hours of the ASC attractive for work/life balance-no evenings, weekend or

holiday hours required of them. If necessary, the ASC may use an agency to find needed staff to supplement its regular staff members.

- 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**

Regarding this consideration, the applicant provided the following information:

This project will introduce the latest technology for the treatment of eye cancer and, together with the already approved COPN No. VA-04812, will introduce into the planning district the most current surgical procedures for eye diseases...The two surgeon owners are also the only surgeons in the vast part of Virginia that specialize in the treatment of ocular tumors, providing a surgical service that is not now available in the Planning District.

- 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.**

Regarding this consideration, the applicant provided the following:

Excellence ASC has a formal collaboration with, and will provide support for, the Eastern Virginia Medical School's Department of Ophthalmology to expand operating room access. This addresses a chronic need of the medical school where lack of access has impaired the quality of education for the physicians in training, and the highly at-risk patients that they uniquely serve. In addition, a similar affiliation arrangement is under way to address the unmet needs of Norfolk State University's Healthcare Sciences to facilitate additional locations and opportunities for clinical rotations. WMRC, and hence Excellence ASC, has a teaching mission. Education and skills transfer facilities are included in the Excellence ASC facility design as a testimony to our commitment to world class education, and a part of the new facility is dedicated to training and clinical rotations.

DCOPN Staff Findings and Conclusion

DCOPN finds that the proposed project to introduce radiation therapy for ocular oncology is generally consistent with the applicable criteria and standards of the SMFP and the eight Required Considerations of the Code of Virginia. As previously discussed, under the status quo, patients requiring treatment for ocular tumors will continue to have to travel great distances for

treatment, experiencing the challenges outlined by the applicant. Furthermore, DCOPN notes that brachytherapy for ocular tumors is offered at only one other provider in the Commonwealth; and that provider is approximately 200 miles from the location of the proposed project. There are no providers of brachytherapy for ocular tumors in PD 20. DCOPN also notes that the applicant will incur very minimal capital costs to operationalize the proposed project and no additional staffing is needed for the proposed project. Therefore, DCOPN concludes that the proposed project is more favorable than maintaining the status quo. Also, DCOPN finds that the total capital costs of the proposed project are modest, and no financing costs will be incurred. Furthermore, DCOPN finds that the project appears to be economically feasible both in the immediate and long-term. Finally, there is no known opposition to the proposed project.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends **conditional approval** of Excellence ASC, LLC's Certificate of Public Need Request number VA-8694 to introduce radiation therapy for ocular oncology for the following reasons:

1. The 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. Radiation therapy for ocular oncology is offered at only one other provider in the Commonwealth, and that provider is approximately 200 miles from the location of the proposed project.
3. There are no providers of brachytherapy for ocular tumors in PD 20.
4. A reasonable, less costly, more efficient alternative to the proposed project does not exist, and the proposed project is more advantageous than maintaining the status quo.
5. There is no known opposition to the project.

DCOPN's recommendation is contingent upon Excellence ASC, LLC's agreement to the following charity care condition:

Excellence ASC, LLC will provide radiation therapy 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 6.0% of Excellence ASC, LLC's total patient services revenue derived from radiation therapy services 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. Excellence ASC, LLC will accept a revised percentage based on the regional average after such time regional

charity care data valued under the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. is available from Virginia Health Information. The value of charity care provided 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.

Excellence ASC, LLC will provide radiation therapy 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 Excellence ASC, LLC will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.

Kelly, Mycal (VDH)

From: Steve Rosenthal <srosenthal7176@gmail.com>
Sent: Monday, September 18, 2023 2:55 PM
To: Cheatham, Valerie (VDH)
Cc: COPN (VDH); Macleod, Vanessa (VDH); kriebling@wagnerretina.com; Alan Wagner; 'Kapoor MD FACS FICS Kapil Gopal'
Subject: RE: Staff Report for COPN Request No. VA-8694
Attachments: 8694 Staff Report Cover Letter - 09-18-23.pdf; 8694 Staff Report FINAL.pdf

Valerie,

Thank you for this.

Excellence ASC, LLC accepts the recommendation for conditional approval of COPN Request No. VA-8694.

Thank you again.

Steve

Stephen D. Rosenthal
SDR LAW, PLC
804.350.8148
srosenthal7176@gmail.com

From: Cheatham, Valerie (VDH) <Valerie.Cheatham@vdh.virginia.gov>
Sent: Monday, September 18, 2023 1:07 PM
To: kriebling@wagnerretina.com; Steve Rosenthal (srosenthal7176@gmail.com) <srosenthal7176@gmail.com>
Cc: COPN (VDH) <COPN@vdh.virginia.gov>; Macleod, Vanessa (VDH) <Vanessa.Macleod@vdh.virginia.gov>
Subject: Staff Report for COPN Request No. VA-8694

Ms. Riebling and Mr. Rosenthal:

I have attached the staff report for COPN Request No. VA-8694. Please let us know if you have any questions.

Thank you,

Valerie

Valerie Cheatham
Certificate of Public Need Analyst
Office of Licensure and Certification

Phone: (804) 367-2370
<https://www.vdh.virginia.gov/licensure-and-certification/>

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