



COMMONWEALTH of VIRGINIA

Colin M. Greene, MD, MPH
State Health Commissioner

Department of Health
P O BOX 2448
RICHMOND, VA 23218

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

October 27, 2022

By Email

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

Certificate of Public Need (COPN)

Number VA-04812

(Request Number VA-8580)

Excellence ASC, LLC

Norfolk, Virginia

Planning District (PD) 20

Health Planning Region V

**Establish an outpatient surgical hospital with two
operating rooms limited to vitreoretinal and
ophthalmic surgery**

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 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.*

Stephen D. Rosenthal, Esquire

October 27, 2022


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Based on my review of this application and on the recommended decision of the adjudication officer, I am approving the application. The project proposed in the application (the “Excellence ASC project,” or “project”) will meet a public need.

The reasons for my decision include the following:

- (i) The Excellence ASC project is consistent with the State Medical Facilities Plan, 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 costs of the project are reasonable;
- (iii) Despite opposition from one existing outpatient surgical hospital, approval of the project would not have an adverse impact on the volume, proficiency or quality of existing surgical services, including ophthalmologic surgical services, in PD 20;
- (iv) Approval of the project would impose an unprecedented level of charity care to PD 20 and beyond; and
- (v) The project would introduce and maintain innovative applications of technology, drugs and procedure particularly beneficial in providing ophthalmologic surgical care that reflect recent developments in saving eyesight, as the population of PD 20 grows and ages.

Sincerely,

DocuSigned by:

80186E196D924B6...
Colin M. Greene, MD, MPH
State Health Commissioner

Encl.: 2

cc (via email):

Parham Jaberi, MD, MPH

Acting Director, Norfolk City 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

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 herein.

NAME OF FACILITY: Excellence ASC.

LOCATION: 863 Glenrock Road, Norfolk, Virginia 23502.

OWNERSHIP AND CONTROL: Excellence ASC, LLC, will maintain ownership of and control over the approved resources.

SCOPE OF PROJECT: Establishment of an outpatient surgical hospital with two (2) operating rooms dedicated and **LIMITED** to ophthalmic surgery, in accordance with representations made during the course of review and adjudication. The total authorized capital cost of the project is \$8,289,491, to be defrayed using accumulated reserves and commercial debt. The project is scheduled to be completed by October 1, 2023. 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 32.1-102.11, 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 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-04812

Date of Issuance: October 27, 2022

Expiration Date: October 26, 2023

DocuSigned by:
Colin M. Greene
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Colin M. Greene, MD, MPH
State Health Commissioner

Condition Placed on the Issuance of this Certificate:

Excellence ASC, LLC, shall provide outpatient vitreoretinal and ophthalmic surgery 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) 20, in an aggregate amount equal to at least **6% of its gross patient revenue derived from surgical services.**

Compliance with this condition shall 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, 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.*, 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.*

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

**Recommended Case Decision
Certificate of Public Need (COPN)
Request Number VA-8580**

**Excellence ASC, LLC
Norfolk, Virginia
Planning District (PD) 20
Health Planning Region V
Establish an outpatient surgical hospital with two
operating rooms limited to vitreoretinal and
ophthalmic surgery**

Introduction

This document is a recommended case decision submitted to the State Health Commissioner (“Commissioner”) for his consideration and adoption. It follows review of the application captioned above that included the convening of an informal fact-finding conference (IFFC),¹ conducted in accordance with the Virginia Administrative Process Act (VAPA)² and Title 32.1 of the Code of Virginia, resulting in preparation of this recommended decision.

Authority

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 this 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

¹ The IFFC was held on August 18, 2022. The IFFC had originally been scheduled for June 7, 2022, and was continued to this later date at the request of the applicant. A certified transcript of the IFFC is in the administrative record.

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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Factual Background

1. The applicant, Excellence ASC, LLC ("Excellence ASC"), is a Virginia limited liability company, the owners of which are ophthalmologists currently providing specialty diagnosis and treatment services at Wagner Macula & Retina Center (WMRC) at 13 clinical office sites, most in PD 20 and 22. The group currently serves patients primarily from the eastern portion of Virginia, the southern portion of Maryland and the eastern portion of North Carolina. It performs a wide array of ophthalmic services including education, public health outreach, screening, as well as a number of clinical trials.

2. Excellence ASC proposes to establish an outpatient surgical hospital (OSH) with two operating rooms (ORs), limited in scope to performing subspecialty vitreoretinal and ophthalmic surgery (including ocular oncological procedures), in Norfolk. These services involve delicate procedures deep within the interior of the eye, and require specially equipped ORs and staff with subspecialty training. Total capital and financing costs for the project (the "Excellence ASC project") are \$8,289,491.

Summary of DCOPN Staff Report

In a staff report dated May 19, 2022, prepared by the Department of Health's Division of Certificate of Public Need (DCOPN) on the Excellence ASC project (the "DCOPN staff report"), that division recommended that the Commissioner deny the Excellence project, relying, in substantial part, on the project's apparent inability to comply with the State Medical Facilities Plan.

Factual Analysis

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

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 cohort of persons age 65 and older uses medical care resources, including surgical services, at a rate higher than the general population. In PD 20, this cohort is expected to grow 32.73 percent from 2020 to 2030, a figure outpacing that for Virginia as a whole.⁶

There are 160 ORs in PD 20. Of this total, 45 ORs are located in OSHs. Of the ORs in OSHs, ten are dedicated and restricted to ophthalmic use. Excellence ASC contends that, of these ten ORs, only two are equipped and staffed for vitreoretinal surgery. These two ORs

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

⁶ DCOPN Proposed Findings and Conclusions at 2.

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are associated with ophthalmologic groups other than WMRC, and Excellence ASC further contends that, practically speaking, only one is arguably available to its ophthalmologists.

Excellence ASC, through an associated research institute, has completed four dozen clinical trials, resulting in significant advances, and is currently participating in 16 trials. These trials require specially-equipped ORs and specially-trained surgical staff.

Excellence ASC further contends that, with the recent closure of Bon Secours DePaul Medical Center, no facility in PD 20, or, indeed, in the entirety of Virginia, has an OR equipped and staffed for ocular oncology surgery, which the two primary ophthalmologists associated with Excellence ASC routinely performs.

Approval of the Excellence ASC project would increase access to healthcare services and provide access to vitreoretinal and ophthalmic surgery services for people in the area to be served, in fact, for residents of Virginia and beyond.

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;⁷ (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.

The Excellence ASC project has garnered substantial public support, including support from the Attorney General, members of the General Assembly representing the area to be served, officials within local governments, businesses, churches, physicians and healthcare providers, and a health care insurer. Bon Secours Surgery Center at Virginia Beach opposes the Excellence ASC project, arguing that no need for additional ORs exists.

Until 2021, the ophthalmologists of WMRC, the group associated with Excellence ASC, performed many surgeries at Bon Secours DePaul Medical Center, which is no longer an operational facility. Regarding alternatives, the applicant maintains that it has requested that OSHs in the area install and make available specific equipment needed for vitreoretinal and ophthalmic surgery, to little or no apparent avail.

⁷ No regional health planning agency currently exists to report on projects proposed in Health Planning Region (HPR) V, which includes PD 20.

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DCOPN states that the total costs of the Excellence ASC project “are significant, but in line with similar projects.”⁸ The benefits from approval of the project include access to a state-of-the-art facility offering an array of ocular surgical procedures.

In relation to the financial accessibility of the project, WMRC has a history of providing a considerable amount of charity care, along with patient outreach. Excellence ASC states that “WMRC will not turn away anyone who needs care.”⁹ Indeed, Excellence ASC proffers its agreement to imposition of a condition on any Certificate that ensues requiring it to provide an amount of charity care equal to or exceeding *six percent of its gross patient revenue*. This figure far exceeds the level of such care provided at any acute-care hospital or OSH in HPR V.

3. The extent to which the proposed project is consistent with the State Health Services Plan [i.e., *de facto*, the SMFP].¹⁰

The COPN law requires that “[a]ny decision to issue . . . a [COPN] shall be consistent with the most recent applicable provisions of the [SMFP]”¹¹ The SMFP, contained in the Virginia Administrative Code (VAC), includes provisions applicable to projects involving radiation therapy services MRI services.

PD 20 has 160 ORs, 45 of which are located in OSHs. Of the ORs in OSHs, ten are dedicated and restricted to ophthalmic use. Using the computational methodology contained in the SMFP, DCOPN calculates that PD 20 has an estimated 2027 surplus of 18 ORs.¹²

Despite this surplus, evidence suggests that the Excellence ASC project, limited in purpose, would meet a specific need by providing valuable, ophthalmic services existing that OSHs, after the closure of Bon Secours DePaul Medical Center, appear unable to accommodate readily. Past COPN approvals have demonstrated the Commissioner’s ability to find, in his discretion, a particularly-beneficial proposed project to be consistent with the SMFP even when a specific provision of the SMFP is not fully satisfied.

In this way, the Excellence ASC 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.¹³

⁸ DCOPN Staff Report at 9.

⁹ Excellence ASC Proposed Findings and Conclusions at 29.

¹⁰ 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 regulation in reviewing applications for a COPN.

¹¹ Va. Code § 32.1-102.3 (B).

¹² At the IFFC, Excellence ASC identified and objected to factual and mathematical errors in the DCOPN Staff Report. DCOPN’s recommendation that the project be denied was based, partially but substantially, on these errors.

¹³ See *Roanoke Mem. Hosp. v. Kenley*, 3 Va. App. 599, 352 S.E.2d 525 (1987).

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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.

Not applicable, without prejudice to the applicant.

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.

The Excellence ASC project would augment the system of health care resources in the area to be served by allowing the incremental introduction of two ORs, to be placed in a specialized OSH under the direct control of surgical specialists dedicated to providing exacting care in the course of routine care, as well as urgent circumstances. The project would have an appropriate and positive relationship to the existing health care system.

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.

The Excellence ASC project is feasible in relation to all particulars specified.

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.

The Excellence ASC project would provide particular innovations and advancements, many until recently unavailable, in the delivery of health care services. The project would include state-of-the-art, up-to-date technology specifically adapted to ophthalmologic surgery. Often, such equipment is bulky and, at the same time, must be mobile in ORs at OSHs that accommodate various types of outpatient surgical procedures. The ORs in the proposed project would be dedicated solely to ophthalmologic surgery, obviating the need to accommodate conflicting types of outpatient surgery.

Further, the project would promote the provision of certain new and emerging treatments and devices, such as drug port devices recently approved by the U.S. Food and Drug Administration. Such innovation can significantly reduce patients' treatment burden, and save eyesight.

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.

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Not directly applicable, without prejudice to the applicant.

Notably, Excellence engages in collaboration with Eastern Virginia Medical School's Department of Ophthalmology to provide and expand medical students' access and ability to observe ophthalmologic surgical care, redressing previous conditions that impaired such access locally, as Excellence ASC states. A similar affiliation may soon exist with Norfolk State University's Healthcare Sciences programs.

Conclusion and Recommendation

As demonstrated by the evidence, the Excellence ASC project would meet a public need under the COPN Law. I recommend that the project be approved.¹⁴

Specific reasons supporting this recommendation include:

- (i) The Excellence ASC 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 costs of the project are reasonable;
- (iii) Despite opposition from one existing OSH, approval of the project would not have an adverse impact on the volume, proficiency or quality of existing surgical services, including ophthalmologic surgical services, in PD 20;
- (iv) Approval of the project would impose an unprecedented level of charity care to PD 20 and beyond; and
- (v) The project would introduce and maintain innovative applications of technology, drugs and procedure particularly beneficial in providing ophthalmologic surgical care that reflect recent developments in saving eyesight, as the population of PD 20 grows and ages.

Respectfully submitted,



October 24, 2022

Douglas R. Harris, JD
Adjudication Officer

¹⁴ Any Certificate resulting from this recommended decision should demonstrate, on its face and in clear terms, that the approval therein is for an OSH consisting of two (2) ORs, and that these ORs are limited to the performance of outpatient ophthalmologic surgery, and that other outpatient surgical procedures cannot be performed without additional approval by the Commissioner.