



October 3, 2022

Gregory F. Yakaboski, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Comments regarding Wake County Operating Room CON Applications

Dear Mr. Yakaboski:

On August 15, 2022, Azura submitted a Certificate of Need (CON) application (CON Project ID# J-12253-22) in response to the need determination in the 2022 SMFP for two (2) additional operating rooms (ORs) in Wake County. Enclosed please find comments prepared by Azura regarding the competing CON applications to develop the need determined ORs in Wake County. We trust that you will take these comments into consideration during your review of all the applications.

If you have any questions about the information presented here, please feel free to contact me at (610) 644-8900. I look forward to seeing you at the public hearing.

Sincerely,

Rhonda Palumbo

Rhonda Palumbo
Director of Business Contracts/Physician Services

**COMMENTS ABOUT COMPETING CERTIFICATE OF NEED APPLICATIONS
WAKE COUNTY OPERATING ROOMS**

**Submitted by Azura Vascular Care
October 3, 2022**

The 2022 *State Medical Facilities Plan (SMFP)* identified a need for two additional operating rooms (ORs) in Wake County. Six providers submitted Certificate of Need (CON) applications to develop new ambulatory surgical facilities (3 applications), a new hospital (one application), or to add ORs to existing health service facilities (2 applications). These applications include:

- J-12248-22 (Project ID #)** KM Surgery Center / Develop a multi-specialty ASF with one OR and two procedure rooms
- J-12252-22 (Project ID #)** Oakview ASC, LLC / Develop a single-specialty ophthalmic ASF with one OR and one procedure room
- J-12253-22 (Project ID #)** Triangle Vascular Care / Develop an ASF with one OR and two procedure rooms for vascular access procedures
- J-12260-22 (Project ID #)** Rex Hospital / Develop two additional operating rooms
- J-12261-22 (Project ID #)** Duke Health Green Level Ambulatory Surgical Center / Develop two additional operating rooms
- J-12264-22 (Project ID #)** WakeMed Garner Hospital / Develop a new hospital, to include two operating rooms

In accordance with N.C. Gen. Stat. § 131E-185(a.1)(1), this document includes comments relating to the representations made by the competing applicants, and a discussion of which of the competing proposals represents the most effective alternative for development of additional ORs in the service area.

Specifically, the Healthcare Planning and Certificate of Need Section, in making the decision, should consider several key issues, including the extent to which each proposed project:

- (1) Best meets the service area need for additional ORs;
- (2) Provides improved geographic access for residents to surgical services;
- (3) Enhances market competition for surgical services and provides local patients with a new alternative source for outpatient surgery in Wake County;

- (4) Maximizes healthcare value in the delivery of health care services for development of the need-determined ORs, with a reasonable project capital cost, and patient access to lower cost surgical services; and
- (5) Demonstrates accessibility for medically underserved groups.

The Agency typically performs a comparative analysis when evaluating the applications in a competitive batch review. The purpose of the comparative analysis is to identify the proposal(s) that would bring the greatest overall benefit to the community. The table on the following page summarizes comparative metrics that the Agency has typically utilized for comparing applications in an operating room batch review, including for the most recent 2021 Wake County OR review.

Wake County Operating Room Batch Review
Applicant Comparative Analysis

Comparative Factor	Triangle Vascular Care	KM Surgery Center	Oakview ASC	Duke Health Green Level ASC	WakeMed Garner Hospital	UNC Rex Hospital
Geographic Accessibility	Most Effective	Less Effective	Less Effective	Least Effective	Less Effective	Least Effective
Competition/ Access to New Provider	Most Effective	More Effective	More Effective	Least Effective	Least Effective	Least Effective
Historical Utilization	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Patient Access to Lower Cost Surgical Services	More Effective	More Effective	More Effective	More Effective	Least Effective	Least Effective
Access by Service Area Residents	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Access by Underserved Groups (Charity Care/Medicare/Medicaid)	Most Effective	Least Effective	Less Effective	Less Effective	Less Effective	Less Effective
Projected Average Net Revenue per Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Average Operating Expense per Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive

Azura notes that three applicants (TVC, KM Surgery Center, and Oakview ASC) propose to develop a new ASF with one operating room. Thus, given the need determination for two additional ORs in Wake County, two of these applicants could be approved, which would be a more beneficial outcome for local residents - in terms of increased access to care - than approval of just one application.

The above comparative analysis shows Triangle Vascular Care ranks most favorably on the comparative metrics, and thus, considering that the Triangle Vascular Care application best achieves the Basic Principles of the 2022 SMFP (Policy GEN-3) of quality, access and value, Triangle Vascular Care is the most effective alternative for development of the need-determined operating rooms in Wake County.

TVC is unique among the applicants for ORs in Wake County in that it represents the only new and innovative model for healthcare delivery in an ASF setting. The other five applications represent either 1) extensions of existing hospital or multi-specialty ASF services (Rex Hospital and Duke Health Green Level ASC), 2) an extremely expensive new hospital (WakeMed Garner Hospital) to be operated by a large existing Wake County hospital system, or 3) single-specialty (Oakview ASC) or multi-specialty (KM Surgery) ASFs for which there are already numerous choices in Wake County.

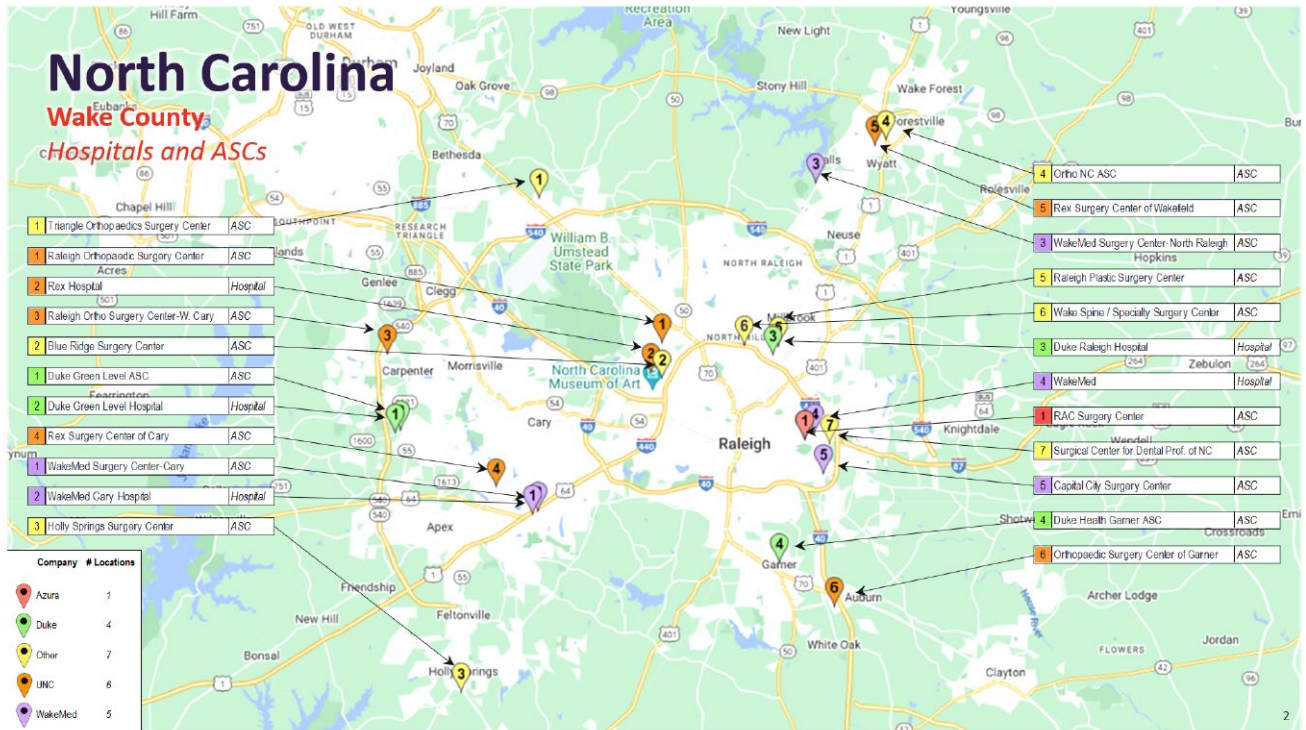
As an ASF, TVC will change the paradigm of care for a unique, large, and growing base of patients with End-stage Renal Disease (ESRD), for whom there is no coordinated system of care in which they can receive the percutaneous and surgical services needed to maintain their ongoing schedule of dialysis. As explained in the TVC CON application, ESRD patients have typically received their vascular access care in a fragmented and costly delivery model, through a combination of physician practice-based procedures, expensive emergency department visits, and hospital inpatient and outpatient surgery procedures. TVC will be able to cost-effectively provide all ESRD or late stage chronic kidney disease (CKD) patient's vascular access needs in one location; from vein mapping and surgical planning, to venography and access creation, to fistula maturation and access maintenance, (thru thrombectomy, angioplasty and stenting). In so doing, TVC will raise the level of the clinical care of an increasing patient population with specific needs. The ESRD patients to be served by TVC are unusual from an ambulatory surgery perspective because their access care tends to be chronic in nature, as opposed to episodic, and patients will typically receive multiple percutaneous and surgical procedures per year, each year during their ongoing dialysis treatment. These patients are also unique due to the urgent/semi-emergent nature of their procedures, often required to be performed the same day in order to maintain vascular access and continue routine dialysis treatment. Only one of the 19 existing or approved Wake County ASFs, and none of the existing hospitals, is currently focused on or designed to meet the specific vascular access needs of this population. This is not sufficient for a county as populous as Wake County. As described in the respective CON applications, none of the competing five OR proposals in this batching cycle will address the needs identified by TVC. In its application, TVC described the benefits of raising the level of care for vascular access procedures to licensed ASFs, and better coordination of care through focused, dedicated ASFs. This is a trend that is occurring nationally and TVC proposes to expand this access to a new, conveniently located Cary location in western Wake County.

As explained in its application, TVC will also offer select non-ESRD vascular treatment procedures (including uterine fibroid treatment, varicoceles, varicose veins, and angioplasty or atherectomy for peripheral artery disease (PAD), which are valuable for many ESRD patients, who may also have PAD.

Review of Comparative Factors

Geographic Accessibility

The map below (also shown on page 88 of TVC’s CON application) portrays all the licensed ambulatory surgical facilities and acute care hospitals with operating rooms that are located in Wake County.



Two of the applications (Duke Health Green Level ASC and UNC Rex Hospital) propose to add operating rooms at existing or approved facilities, and thus, are the least effective alternatives from the perspective of enhancing geographic access.

Of the remaining four applications, one (TVC) proposes to develop an ASF in Cary, two propose to develop ASFs in Raleigh, and one (WakeMed Garner Hospital) proposes to develop ORs in Garner.

The table below portrays a comparison of the current local access to operating rooms, based on evaluating the municipal population and the number of existing and approved ambulatory operating rooms in that municipality.

Ratio of Population to Operating Rooms for Wake County Municipalities

Municipality	2021 Population	Ambulatory Operating Rooms	Pop/OR Ratio
Raleigh	469,124	28	16,754
Cary	176,987	7	25,284
Garner	31,935	3	10,645

Sources: Population, U.S. Census Bureau; ORs, Proposed 2023 SMFP

As shown in the table above, Cary currently has the highest population per ambulatory operating room, which means Cary has the worst per capita OR access compared to Raleigh and to Garner. Therefore, the TVC application is the most effective alternative with regard to geographic accessibility.

Competition/Access to New Provider

Generally, the application proposing to increase competition and patient access to a new or alternative provider in the service area is the more effective alternative with regard to this comparative factor. According to the Proposed 2023 State Medical Facilities Plan (SMFP), there are currently 119 existing or approved ORs (excluding dedicated C-Section and trauma ORs) in the Wake County OR service area. Duke Health, WakeMed and UNC Rex are existing providers of surgical services in Wake County, as shown on the following table.

Proposed 2023 SMFP Table 6A – Wake County Operating Room Inventory

Service Area	License	Facility	Inpatient ORs	Ambulatory ORs	Shared ORs	Excluded C-Section ORs	Excluded Trauma/Burn ORs	CON Adjustments	CONs for Excluded C-Section ORs
Vance/Warren Total			0	0	5	0	0	0	0
Wake		Duke Green Level Hospital	0	0	0	0	0	2	0
Wake		Duke Health Garner Ambulatory Surgical Center	0	0	0	0	0	1	0
Wake		Duke Health Green Level Ambulatory Surgery Center	0	0	0	0	0	1	0
Wake	H0238	Duke Raleigh Hospital	0	0	15	0	0	-2	0
Duke University Health System Total			0	0	15	0	0	2	0
Wake		Orthopaedic Surgery Center of Garner	0	0	0	0	0	1	0
Wake	AS0129	Rex Surgery Center of Cary	0	4	0	0	0	0	0
Wake	AS0143	Raleigh Orthopaedic Surgery Center	0	3	0	0	0	1	0
Wake	AS0160	Rex Surgery Center of Wakefield	0	2	0	0	0	0	0
Wake	AS0171	Raleigh Orthopaedic Surgery Center-West Cary	0	1	0	0	0	0	0
Wake	H0065	Rex Hospital	4	0	27	-4	0	1	1
UNC Health Total			4	10	27	-4	0	3	1
Wake		WakeMed Surgery Center-Cary	0	0	0	0	0	1	0
Wake		WakeMed Surgery Center-North Raleigh	0	0	0	0	0	1	0
Wake	AS0137	Capital City Surgery Center	0	8	0	0	0	-1	0
Wake	H0199	WakeMed	8	0	20	-4	-1	0	0
Wake	H0276	WakeMed Cary Hospital	2	0	9	-2	0	1	0
WakeMed Health & Hospitals Total			10	8	29	-6	-1	2	0

Source: Proposed 2023 SMFP, Table 6A

If Duke Health’s application is approved, Duke would control 19 of the 121 existing and approved ORs located in Wake County, or 15.7% percent. If WakeMed’s application is approved, WakeMed would control 44 of the 121 existing and approved ORs located in Wake County, or 36.4% percent. If UNC Rex’s application is approved, UNC Health would control 40 of the 121 existing and approved ORs located in Wake County, or 33.1% percent. Together, these three entities currently control 97 of the 121 existing and approved ORs located in Wake County, or 80.2% percent.

Clearly therefore, with regard to competition, the applications submitted by Duke Health, WakeMed, and UNC Rex are less effective alternatives, and the applications submitted by TVC, KM Surgery Center, and Oakview ASC are the more effective alternatives. Further, both KM Surgery Center and Oakview ASC offer surgical specialties that are already readily available at many other existing or approved Wake County ASFs. Therefore, of the three new ASF proposals, the TVC application is the most effective alternative as to access to a new provider.

Historical Utilization

Of the six applications in this OR batch review, only one (Rex Hospital) is for an existing facility that reported utilization in FFY2021. The other five applications are for 1) expansion of a previously approved but not yet developed facility (Duke Health Green Level ASC) or 2) are proposed new facilities (TVC, KM Surgery Center, Oakview ASC, and WakeMed Garner Hospital). Thus, this comparative is inconclusive and of no value in this review.

Patient Access to Lower Cost Surgical Services

According to the Proposed 2023 SMFP, there are currently 119 existing or approved ORs (excluding dedicated C-Section and trauma ORs) in the Wake County OR service area. ORs can be licensed as part of a hospital or an ASF. Many outpatient surgical services can be appropriately performed in either a hospital-based OR (either shared inpatient/outpatient ORs or dedicated ambulatory surgery ORs) or in an OR located at an ASF. However, the cost for that same service will often be much higher if performed in a hospital-based OR, or conversely, much less expensive if performed in an OR located at an ASF. While many outpatient surgical services can be performed in an OR located at an ASF, not all of them are appropriate for an OR located at an ASF, and inpatient surgical services must be performed in a hospital-based OR.

According to the Proposed 2023 SMFP, an average of 75.7% percent (67,268/88,842) of the total Wake County surgical cases in FFY2021 were outpatient surgical cases. Wake County currently has a total of 33 dedicated ambulatory ORs (either in an ASF or dedicated ambulatory ORs in a hospital setting). Based on the fact that 76% of Wake County's FFY2021 surgical cases were ambulatory surgery cases, and that dedicated ambulatory surgery ORs represent just 27.7% (33/119) of the total existing and approved Wake County ORs, the applications proposing development of dedicated ambulatory surgery ORs represent more effective alternatives.

Therefore, the applications submitted by TVC, KM Surgery Center, Oakview ASC, and Duke Health Green Level ASC are the more effective proposals with respect to this comparative factor. The two hospital applications (WakeMed Garner Hospital and UNC Rex Hospital) are the least effective proposals.

Access by Service Area Residents

The 2022 SMFP shows Wake County as its own OR service area; thus, the service area for this review is Wake County. Facilities may also serve residents of counties not

included in their service area. The application projecting to serve the highest percentage of Wake County residents could be considered the more effective alternative with regard to this comparative factor since the need determination is for additional ORs to be located in Wake County. However, differences in the acuity level of patients at each facility, the level of care (community hospital, tertiary care hospital, inpatient / ambulatory surgical services, etc.) at each facility, and the number and types of surgical services proposed by each of the facilities may impact the projected patient origin by county. For example, the lack of access for North Carolina residents to vascular access surgical services is reflected in the broad geographic patient origin shown in the TVC application. Residents from throughout North Carolina are seeking access to vascular access surgical services wherever it may be available, even in counties away from their homes. Thus, the result of this analysis is inconclusive and of no value in this review.

Access by Medically Underserved Groups

“Underserved groups” is defined in G.S. 131E-183(a)(13) as follows:

“Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority.”

The following table shows projected combined charity care/Medicare/Medicaid during the third full fiscal year following project completion for each facility. Generally, the application projecting to provide the most charity care, Medicare and Medicaid is the more effective alternative with regard to this comparative factor.

Projected Combined Charity Care, Medicare & Medicaid Percentage of Patients (Project Year 3)

Applicant	Charity Care %	Medicare %	Medicaid %	Combined
TVC	1.0%	82.06%	4.41%	87.47%
KM Surgery Center	1.8%	29.5%	1.9%	33.2%
Oakview ASC	3.0%	72.3%	0.5%	75.8%
Duke Health Green Level ASC	2.3%	40.9%	6.0%	49.2%
WakeMed Garner*	7.77%	41.0%	14.02%	62.79%
UNC Rex Hosp.**	3.1%	40.9%	4.3%	48.3%

Source: Section L.3 for each applicant.

*Outpatient surgery.

**Combined inpatient & outpatient surgery.

As shown in the table above, in regard to OR services, TVC projects the highest combined charity care/Medicare/Medicaid as a percent of total patients served. Therefore, the TVC application is the more effective alternative with regard to access to surgical services for medically underserved groups, and the applications submitted by KM Surgery Center, Oakview ASC, Duke Health Green Level ASC, WakeMed Garner Hospital, and UNC Rex Hospital are all less effective alternatives.

Projected Average Net Revenue per Case

The following table shows the projected average net surgical revenue per surgical case in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average net revenue per surgical case is the more effective alternative with regard to this comparative factor to the extent the average reflects a lower cost to the patient or third-party payor.

Projected Average Net Revenue per Case (Project Year 3)

Applicant	Total # of Surgical Cases	Net Revenues for Surgical Services	Net Revenue per Surgical Case
TVC	729	\$4,226,955	\$5,798
KM Surgery Center*	4,083	\$7,074,418	\$1,733
Oakview ASC	2,495	\$2,722,058	\$1,091
Duke Health Green Level ASC	3,279	\$15,663,253	\$4,777
WakeMed Garner	1,980	\$16,377,138	\$8,271
UNC Rex Hospital	22,776	\$252,596,640	\$11,090

Source: Form F.2b for each applicant.

*Totals include revenues and cases performed in both the OR and the procedure rooms.

The four ASFs project the lowest average net revenue per case, as compared to the two hospital applications. However, differences in the acuity level of patients at each facility, the level of care (community hospital, tertiary care hospital, inpatient/ambulatory surgical services, etc.) at each facility, and the number and types of surgical services proposed by each of the facilities may impact the averages shown in the table above. Also, the KM Surgery Center application did not separate the projected OR revenues from the projected procedure room revenues. Thus, the result of this analysis is inconclusive.

Projected Average Operating Expense per Case

The following table shows the projected average operating expense per surgical case in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average operating expense per surgical case is the more effective alternative with regard to this comparative factor to the extent the average reflects a more cost-effective service which could also result in lower costs to the patient or third-party payor.

Projected Average Operating Expenses per Case (Project Year 3)

Applicant	Total # of Surgical Cases	Operating Expenses for Surgical Services	Operating Expense per Surgical Case
TVC	729	\$2,149,140	\$2,948
KM Surgery Center*	4,083	\$5,076,781	\$1,243
Oakview ASC	2,495	\$2,452,508	\$983
Duke Health Green Level ASC	3,279	\$11,289,982	\$3,443
WakeMed Garner	1,980	\$16,923,587	\$8,547
UNC Rex Hospital	22,776	\$205,748,067	\$9,034

Source: Form F.2b for each applicant.

*Totals include expenses and cases performed in both the OR and the procedure rooms.

The four ASFs project the lowest average operating expense per case, as compared to the two hospital applications. However, differences in the acuity level of patients at each facility, the level of care (community hospital, tertiary care hospital, inpatient / ambulatory surgical services, etc.) at each facility, and the number and types of surgical services proposed by each of the facilities may impact the averages shown in the table above. Also, the KM Surgery Center application did not separate the projected OR expenses from the projected procedure room expenses. Thus, the result of this analysis is inconclusive.

Conclusion

As described in the above comparative analysis, Triangle Vascular Care ranks most favorably on the comparative metrics, and is the most effective alternative for development of the need-determined operating rooms in Wake County.

Azura proposes to develop its ASF project and bring the OR online quicker (by January 1, 2024) than any other applicant in this review. None of the proposed projects discussed above address the needs that TVC identifies in its application for ESRD

patients. Without ready and convenient geographic access to an ASF that is focused on vascular access patients as TVC proposes, these vulnerable patients are hospitalized for their vascular access needs. Hospitalization creates major health risks for this vulnerable population and is the most expensive setting for vascular access care. For instance, in comparison to hospital-based fistula creation and revision, the proposed ESRD-ASF is a more cost-effective site of service. These patients are better cared for in a licensed ASF setting focused solely on the ESRD and vascular-access patient needs.

TVC is seeking one OR and two procedure room to provide services specifically to the growing vascular access patient population. As previously established, this patient population is vulnerable and requires coordinated, specialized care. The other applications propose to provide services that are currently already offered in the service area by one provider or another. Further, two out of the five other applications are hospital-based projects. As detailed in TVC's application, the hospital setting is much more costly and exposes ESRD patients with weakened immune systems, potentially risking patient safety. The other proposed ASFs do not offer the types of services that TVC proposes to offer to meet the needs of the vascular access population. Azura contends that its proposed project for an ASF with one OR and two procedure rooms should be approved in order to ensure that ESRD and other vascular access patients in Wake County have adequate access to the services they need, and that no other applicant proposes to serve.