



July 31, 2023

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 Pitt County Operating Room CON Applications

Dear Mr. Yakaboski:

On June 15, 2023, Eastern Nephrology Associates ASC (ENAASC) submitted a Certificate of Need (CON) application (CON Project ID# Q-12397-23) in response to the need determination in the 2023 SMFP for three (3) additional operating rooms (ORs) in the Pitt/Greene/Hyde/Tyrell Service Area. Enclosed please find written comments regarding the two CON applications filed in the Service Area batch review. We trust that you will take these comments into consideration during your review of both applications.

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

Sincerely,

Rhonda Palumbo

Rhonda Palumbo
Director of Business Contracts/Physician Services

**COMMENTS ABOUT CERTIFICATE OF NEED APPLICATIONS
TO DEVELOP OPERATING ROOMS IN PITT COUNTY**

**Submitted by Eastern Nephrology Associates ASC
July 31, 2023**

The 2023 *State Medical Facilities Plan (SMFP)* identified a need for three additional operating rooms (ORs) in the Pitt/Greene/Hyde/Tyrell Operating Room Service Area. Two providers submitted Certificate of Need (CON) applications to develop a total of four (4) new operating rooms. These applications include:

Q-12397-23 (Project ID #) Eastern Nephrology Associates ASC / Develop an ASF with one OR and three procedure rooms for vascular access procedures

Q-12392-23 (Project ID #) Pitt County Memorial Hospital / Develop three additional 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 two applicants, and a discussion of which of the proposals represents the most effective alternative for development of additional ORs in the service area.

ENAASC notes that the two applicants propose to develop a combined total of four operating rooms. Thus, given the need determination for three additional ORs in the Pitt/Greene/Hyde/Tyrell Service Area, the Agency could approve both applicants (approve one OR for ENAASC and two ORs for Vidant Medical Center (name recently changed to ECU Health Medical Center)), which would be a more beneficial outcome for local residents - in terms of increased access to care and enhanced access to a new provider - than approval of just one application.

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.

Pitt/Greene/Hyde/Tyrell Operating Room Service Area Batch Review

Applicant Comparative Analysis

Comparative Factor	Eastern Nephrology Associates ASC	ECU Health Medical Center
Geographic Accessibility	Equally Effective	Equally Effective
Competition/ Access to New Provider	Most Effective	Least Effective
Historical Utilization	Inconclusive	Inconclusive
Patient Access to Lower Cost Surgical Services	Most Effective	Least Effective
Access by Service Area Residents	Inconclusive	Inconclusive
Access by Underserved Groups (Charity Care/Medicare/Medicaid)	Inconclusive	Inconclusive
Projected Average Net Revenue per Case	Inconclusive	Inconclusive
Projected Average Operating Expense per Case	Inconclusive	Inconclusive

The above comparative analysis shows ENAASC ranks most favorably on the comparative metrics, and thus, considering that the ENAASC application best achieves the Basic Principles of the 2023 SMFP (Policy GEN-3) of quality, access and value, ENAASC is the most effective alternative for development of a need-determined operating room in the Pitt/Greene/Hyde/Tyrell Service Area.

ENAASC is unique among the two applicants in that it represents a new and innovative model for healthcare delivery in an ASF setting. The ECU Health Medical Center application represents an expansion of the existing hospital.

As an ASF, ENAASC 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 ENAASC 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. ENAASC 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, ENAASC will raise the level of the clinical care of an increasing patient population with specific needs. As explained in its application, the ESRD patients to be served by ENAASC 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. Neither EHMC nor the ECU Health SurgiCenter (the only two licensed facilities in Pitt County) is currently focused on or designed to meet the specific vascular access needs of this population. The EHMC OR proposal in this batching cycle does not represent any new service offering, and thus will not as beneficially address the needs identified by ENAASC. In its application, ENAASC described the benefits of raising the level of care for vascular access procedures to licensed ASFs, and better coordination of care, and increased value to the patient, through focused, dedicated ASFs. This is a trend that is occurring nationally, and ENAASC proposes to expand this access to a new, conveniently located Pitt County location.

As explained in its application, ENAASC 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

Both applicants propose to develop the additional operating rooms in Greenville. Therefore, the applications are equally 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 2023 State Medical Facilities Plan (SMFP), there are currently 44 existing or approved ORs in Pitt County. As shown on the SMFP excerpt below, ECU Health operates all of them (note the table reflects the former “Vidant” naming convention).

2023 SMFP Table 6A – Pitt County Operating Room Inventory

Table 6A: Operating Room Inventory and Grouping (Combined Data for Hospitals and Ambulatory Surgical Facilities)

Case data for 10/1/2020 through 9/30/2021 as reported on the 2022 Hospital and Ambulatory Surgical Facility License Renewal Applications

A	B	C	D	E	F	G	H	I	J	K	L	M
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	Total Surgical Hours for Grouping	Group	Standard Hours per OR per Year
New Hanover Total			5	13	29	-3	-1	8	0			
Onslow	H0048	Onslow Memorial Hospital	1	4	5	-1	0	0	0	6,970.0	4	1,500
Onslow Total			1	4	5	-1	0	0	0			
Orange		North Chapel Hill Surgery Center	0	0	0	0	0	2	0	0.0		
Orange	H0157	University of North Carolina Hospitals	3	6	37	-3	-2	11	0	92,723.1	1	1,950
UNC Health Total			3	6	37	-3	-2	13	0			
Orange		Duke Health Orange Ambulatory Surgical Center	0	0	0	0	0	2	0	0.0		
Orange Total			3	6	37	-3	-2	15	0			
Pasquotank	H0054	Sentara Albemarle Medical Center	2	0	8	-2	0	0	0	5,350.5	4	1,500
Pasq-Cam-Cur-Gates-Perq Total			2	0	8	-2	0	0	0			
Pender	H0115	Pender Memorial Hospital	0	0	2	0	0	0	0	2,737.2	4	1,500
Pender Total			0	0	2	0	0	0	0			
Person	H0066	Person Memorial Hospital	1	0	4	-1	0	0	0	416.8	4	1,500
Person Total			1	0	4	-1	0	0	0			
Pitt	AS0012	Vidant SurgiCenter	0	10	0	0	0	0	0	15,448.0	6	1,312
Pitt	H0104	Vidant Medical Center	7	0	26	-4	-1	1	0	57,838.5	1	1,950
Vidant Health Total			7	10	26	-4	-1	1	0			
Pitt/Greene/Hyde/Tyrell Total			7	10	26	-4	-1	1	0			
Polk	H0079	St. Luke's Hospital	0	0	3	0	0	0	0	1,091.2	4	1,500
Polk Total			0	0	3	0	0	0	0			
Randolph	H0013	Randolph Hospital	1	2	5	-1	0	0	0	4,467.5	4	1,500
Randolph Total			1	2	5	-1	0	0	0			
Richmond	H0158	FirstHealth Moore Regional Hospital - Richmond	1	0	3	-1	0	0	0	2,054.4	4	1,500
Richmond Total			1	0	3	-1	0	0	0			
Robeson	AS0150	The Surgery Center at Southeastern Health Park	0	4	0	0	0	0	0	692.5	5	1,312
Robeson	H0064	Southeastern Regional Medical Center	2	0	5	-1	0	0	0	6,800.9	4	1,500

Source: 2023 SMFP, Table 6A

If only ECU Health's application is approved, ECU Health would continue to control 100% of the existing and approved ORs located in Pitt County. Clearly therefore, with regard to competition, the application submitted by ECU Health is a less effective alternative, and the application submitted by ENAASC represents the beneficial addition of a new provider in the OR Service Area. Therefore, the ENAASC application is the most effective alternative as to access to competition and access to a new provider.

Historical Utilization

Of the two applications in this OR batch review, only one (ECU Health Medical Center) is for an existing facility that reported utilization in FFY2022. The ENAASC application is for a proposed new facility. Thus, this comparative is inconclusive and of no value in this review.

Patient Access to Lower Cost Surgical Services

According to the Proposed 2024 SMFP, there are currently 44 existing or approved ORs in the Pitt/Greene/Hyde/Tyrell OR service area. Operating rooms 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 Table 6B of the Proposed 2024 SMFP, 68.4% (22,954/33,546) of the total Pitt County (Greene, Hyde and Tyrell counties do not host any operating rooms) surgical cases in FFY2022 were outpatient surgical cases. Pitt County currently has a total of 10 dedicated ambulatory ORs (at ECU Health SurgiCenter). Based on the fact that 68% of Pitt County's FFY2022 surgical cases were ambulatory surgery cases, and that dedicated ambulatory surgery ORs represent just 22.7% (10/44) of the total existing and approved Pitt County ORs, the ENAASC application proposing development of dedicated ambulatory surgery ORs represents the more effective alternative. The ECU Health hospital application is the least effective proposal.

Access by Service Area Residents

The 2023 SMFP indicates that the OR Service Area for this review includes Pitt, Greene, Hyde and Tyrell counties. Facilities may also serve residents of counties not included in their service area. The application projecting to serve the highest percentage of OR Service Area 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 the four-county OR Service Area. However, differences in the acuity level of patients at each facility, the level of care (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 eastern North Carolina residents to vascular access surgical services is reflected in the broad geographic patient origin shown in the ENAASC 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 may be viewed as inconclusive 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 applicant. 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
ENAASC	0.80%	88.10%	4.90%	93.80%
EHMC*	5.70%	43.10%	15.60%	64.40%

Source: Section L.3 for each applicant.

*Combined inpatient & outpatient surgery.

As shown in the table above, in regard to OR services, ENAASC projects the highest combined charity care/Medicare/Medicaid as a percent of total patients served.

Therefore, generally the ENAASC application would be the more effective alternative with regard to access to surgical services for medically underserved groups, and the ECU Health Medical Center application would be a less effective alternative. However, due to differences in the acuity level of patients at each facility, the level of care (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, the result of this analysis may be viewed as inconclusive in this review.

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 applicant. 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
ENAASC	711	\$3,444,109	\$4,844
EHMC	15,203	\$517,052,902*	\$34,010*

Source: Form F.2b for each applicant.

*Totals include combined inpatient & outpatient surgery revenues.

The proposed ENAASC ASF projects the lowest average net revenue per case, as compared to the hospital application. However, differences in the acuity level of patients at each facility, the level of care (ASF, 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 EHMC application did not project inpatient and outpatient surgery revenues separately. Thus, the result of this analysis may be viewed as inconclusive in this review.

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 applicant. 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
ENAASC	711	\$2,307,590	\$3,246
EHMC	15,203	\$462,534,005*	\$30,424*

Source: Form F.2b for each applicant.

* Totals include combined inpatient & outpatient surgery revenues.

The proposed ENAASC ASF projects the lowest average operating expense per case, as compared to the hospital application. However, differences in the acuity level of patients at each facility, the level of care (ASF, 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 EHMC application did not project inpatient and outpatient surgery operating expenses separately. Thus, the result of this analysis may be viewed as inconclusive in this review.

Conclusion

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

Without ready and convenient geographic access to an ASF that is focused on vascular access patients as ENAASC proposes, these vulnerable patients are hospitalized for their vascular access needs. Hospitalization creates 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 vascular access ASF is a more cost-effective site of service. These patients are better cared for in a licensed ASF setting focused solely on ESRD and vascular-access patient needs.

ENAASC is seeking one OR and three procedure rooms 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

hospital application proposes providing hospital-based services that are currently already offered in the service area. As detailed in ENAASC's application, the hospital setting is more costly, and potentially exposes ESRD patients with weakened immune systems to hospital-borne pathogens. ENAASC contends that its proposed project for an ASF with one OR and three procedure rooms should be approved in order to ensure that ESRD and other vascular access patients in the Pitt/Greene/Hyde/Tyrell OR Service Area have adequate and appropriate access to the outpatient services they need.