

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: November 27, 2023

Findings Date: November 27, 2023

Project Analyst: Gregory F. Yakaboski

Co-Signer: Lisa Pittman

COMPETITIVE REVIEW

Project ID #: Q-12392-23
Facility: ECU Health Medical Center
FID #: 933410
County: Pitt
Applicant: Pitt County Memorial Hospital, Inc.
Project: Develop no more than three ORs pursuant to the 2023 SMFP need determination for a total of 37 ORs, including 4 dedicated C-Section ORs and 1 Trauma OR.

Project ID #: Q-12397-23
Facility: Eastern Nephrology Associates ASC
FID #: 230544
County: Pitt
Applicants: Eastern Nephrology Associates ASC, LLC
Fresenius Vascular Care Greenville MSO, LLC
Project: Develop a new ASC with no more than one single specialty dedicated vascular OR pursuant to 2023 SMFP need determination and three procedure rooms

Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Need Determination

In the 2023 SMFP, Table 6C: *Operating Room Need Determination* shows a need determination for three ORs in the Pitt/Green/Hyde/Tyrell County operating room (OR) service area. Two applications were submitted to the CON Section, proposing to develop a total of four ORs. However, pursuant to the need determination, only three ORs may be approved in this review for the Pitt/Green/Hyde/Tyrell OR service area. See the Conclusion following the Comparative Analysis for the decision.

Policies

There are two policies in the 2023 SMFP which are applicable to this review: *Policy GEN-3: Basic Principles* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy GEN-3: Basic Principles, on page 30 of the 2023 SMFP, states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 30 of the 2023 SMFP, states:

“Any person proposing a capital expenditure greater than \$4 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall

include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

Project ID# Q-12392-23/ ECU Health Medical Center/ Add three ORs

The applicant, **Pitt County Memorial Hospital, Inc.**, hereinafter referred to as "the applicant" or PCMH Inc., proposes to add three ORs at the ECU Health Medical Center (ECU Medical Center or EHMC) pursuant to the need determination in the 2023 SMFP. The ECU Medical Center is an acute care hospital and is located at 2100 Stantonsburg Road, Greenville. ECU Medical Center has ORs located in two separate OR suites: the main hospital (Main OR) and the ECU Medical Center Heart Institute (ECHI) tower, hereinafter referred to as "CV OR", which is adjacent to and connected to Main OR. ECU Medical Center has 29 ORs (excluding 4 dedicated C-Section rooms and one Trauma/Burn OR). Main OR has 22 ORs and ECHI has 7 ORs. Upon project completion ECU Medical Center would have 32 ORs excluding the 4 dedicated C-Section ORs and the one Trauma/Burn OR. ECU Health Medical Center was previously known as Vidant Medical Center.

Need Determination. The applicant does not propose to develop more ORs than are determined to be needed.

Policy GEN-3. In Section B, pages 26-28, the applicant explains why it believes its application is conforming to Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this project is greater than \$5 million. In Section B, page 29, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more ORs than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 for the following reasons:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of OR services in the Pitt/Green/Hyde/Tyrell OR service area; and
 - The applicant adequately documents how the project will promote equitable access to OR services in the Pitt/Green/Hyde/Tyrell OR service area; and
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
 - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Project ID# Q-12397-23/ Eastern Nephrology Associates ASC/ Develop a new ASF with no more than one single specialty dedicated vascular OR and three procedure rooms

The applicants, Eastern Nephrology Associates ASC, LLC and Fresenius Vascular Care Greenville MSO, LLC, hereinafter referred to as “the applicant” or Fresenius, propose to develop a new ambulatory surgical facility (ASF) [Eastern Nephrology Associates ASC (Eastern Nephrology ASC or ENAASC)] with no more than one single specialty dedicated vascular OR pursuant to the need determination in the 2023 SMFP and three procedure rooms. Eastern Nephrology ASC is to be located at 2300 Emerald Place, Greenville. The applicant plans to lease and upfit shell space in a new medical office building.

Need Determination. The applicant does not propose to develop more ORs than are determined to be needed.

Policy GEN-3. In Section B, pages 26-27, the applicant explains why it believes its application is conforming to Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this project is greater than \$5 million. In Section B, pages 27-28, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more ORs than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 for the following reasons:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of OR services in the Pitt/Green/Hyde/Tyrell OR service area; and
 - The applicant adequately documents how the project will promote equitable access to OR services in the Pitt/Green/Hyde/Tyrell OR service area; and
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
 - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

Project ID# Q-12392-23/ ECU Medical Center/ Add three ORs

The applicant proposes to add a total of three ORs at ECU Medical Center. Two of the three ORs would be added to Main OR in previously decommissioned operating rooms. The third OR is proposed to be added to CV OR. The OR proposed to be added at CV OR would be a hybrid OR. Upon project completion ECU Medical Center would have 32 ORs excluding the 4 dedicated C-Section ORs and one Trauma/Burn OR.

Patient Origin

N.C.G.S. §131E-176(24a) states: “Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.” On page 47, the 2023 SMFP states, “An OR’s service area is the single or multicounty grouping shown in Figure 6.1.” ECU Medical Center is in Pitt County. In Figure 6.1, page 53 of the 2023 SMFP, Pitt County is shown as part of the Pitt/Greene/Hyde/Tyrrell multicounty operating room service area. Thus, the operating room service area for this facility consists of Pitt, Greene, Hyde and Tyrrell counties. Facilities may also serve residents of counties not included in the service area.

The following table illustrates historical and projected patient origin.

County	Historical (10/1/2021 – 9/30/2022)		Third Full FY of Operation following Project Completion (10/1/2028 – 9/30/2029)	
	Patients	% of Total	Patients	% of Total
Pitt	7,110	32.3%	8,603	32.3%
Beaufort	1,626	7.4%	1,967	7.4%
Lenoir	1,269	5.8%	1,535	5.8%
Wayne	1,035	4.7%	1,252	4.7%
Edgecombe	1,033	4.7%	1,250	4.7%
Craven	944	4.3%	1,142	4.3%
Wilson	906	4.1%	1,096	4.1%
Martin	905	4.1%	1,095	4.1%
Halifax	715	3.2%	865	3.2%
Onslow	701	3.2%	848	3.2%
Nash	658	3.0%	796	3.0%
Bertie	582	2.6%	704	2.6%
Greene	545	2.5%	659	2.5%
Duplin	497	2.3%	601	2.3%
Hertford	478	2.2%	578	2.2%
Carteret	448	2.0%	542	2.0%
Washington	377	1.7%	456	1.7%
Northampton	282	1.3%	341	1.3%
Chowan	267	1.2%	323	1.2%
All Other (<1.0%)	1,665	7.6%	2,015	7.6%
Total	22,043	100.0%	26,672	100.0%

Source: Tables on pages 34 & 36 of the application.

In Section C, page 35, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on the applicant's historical (FY22) patient origin for surgical services at ECU Medical Center.

Analysis of Need

In Section C, pages 38-48, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Address ECU Medical Center's Historical and Projected Surgical Growth & Capacity Constraints (see pages 39-42).
- Maintain Adequate Capacity to Meet the Needs of the Medically Underserved (see pages 42-43).
- Maintain Adequate Capacity to Meet the Need for Complex Care (see pages 43-44).
- Maintain Capacity to Continue to be a Regional Resource to Serve all ENC (see pages 43-44).
- Maintain Capacity to Continue to Provide a Broad Scope of Services to Both IP and OP (see pages 44-45).
- Increase Patient Satisfaction and Physician Satisfaction (see page 45).
- Maintain Adequate Capacity for Education and Research (see page 46).
- Address the Need for Using One OR as a Hybrid OR (see pages 46-48)

The information is reasonable and adequately supported based on the following:

- The 2023 SMFP includes a need determination for three additional ORs in the Pitt/Greene/Hyde/Tyrell multicounty operating room service area and currently the only ORs in that service area are all part of the ECU Health System. The surgical case volume generated by the ECU Health System thus triggered the OR need determination.
- The applicant provides information and data to support their assertions regarding the historical growth in surgical case volumes at ECU Medical Center.
- The applicant documented capacity constraints in servicing existing and projected ECU Medical Center patient need for surgical services.
- The applicant documents how additional ORs would address labor and operational costs, quality of care and improve patient satisfaction, staff and physician morale, recruitment and retention.

Projected Utilization

Pursuant to 10A NCAC 14C .2103(a), the applicant must demonstrate the need for all existing, approved, and proposed ORs in the health system at the end of the third full fiscal year following project completion, using the Operating Room Need Methodology in the 2023 SMFP. Health system is defined in 10A NCAC 14C .2101 and in Chapter 6 Operating Rooms,

page 47 of the 2023 SMFP. Pursuant to the definition of health system ECU Medical Center Care is part of the same health system as ECU SurgiCenter which, for this review, will be referred to as the ECU Health System. ECU Medical Center and ECU SurgiCenter are related entities, but separately licensed.

ECU Medical Center

In Section Q, Forms C.3a and C.3b, pages 105-108, the applicant provides historic, interim and projected utilization at ECU Medical Center, as illustrated in the following tables.

ECU Medical Center: Historic, Interim and Projected OR Cases

Surgical Cases	Historical FFY 2022	Interim FFY 2023	Interim FFY2024	Interim FFY2025
# of ORs*	28	29	29	31
IP Cases	10,510	10,830	11,156	11,365
OP Cases	11,533	12,656	13,363	13,890
Total Cases**	22,043	23,486	24,519	25,255

*# of ORs does not include the four dedicated C-section ORs and the one Trauma/Burn OR.

**Total Cases does not include C-Section cases performed in dedicated C-Section ORs.

ECU Medical Center: Historic, Interim and Projected OR Cases

Surgical Cases	Partial Interim FFY2026	Partial FFY2026	Year 1 FFY 2027	Year 2 FFY 2028	Year 3 FFY 2029
# of ORs*	31	32	32	32	32
IP Cases	5,732	5,732	11,504	11,487	11,469
OP Cases	7,148	7,148	14,642	14,920	15,203
Total Cases**	12,880	12,880	26,146	26,407	26,672

*# of ORs does not include the four dedicated C-section ORs and the one Trauma/Burn OR.

**Total Cases does not include C-Section cases performed in dedicated C-Section ORs.

SurgiCenter

In Section Q, Forms C.3a and C.3b, pages 109-112, the applicant provides historic, interim and projected utilization at SurgiCenter, as illustrated in the following tables.

SurgiCenter: Historic, Interim and Projected OR Cases

Surgical Cases	Historical FFY 2022	Interim FFY 2023	Interim FFY2024	Interim FFY2025
# of ORs	10	10	10	10
IP Cases	0	0	0	0
OP Cases	11,418	11,530	11,645	11,762
Total Cases	11,418	11,530	11,645	11,762

SurgiCenter: Historic, Interim and Projected OR Cases

Surgical Cases	Partial Interim FFY2026	Partial FFY2026	Year 1 FFY 2027	Year 2 FFY 2028	Year 3 FFY 2029
# of ORs	10	10	10	10	10
IP Cases	0	0	0	0	0
OP Cases	5,940	5,940	11,998	12,118	12,239
Total Cases	5,940	5,940	11,998	12,118	12,239

In Section Q, Form C.2&3 *Utilization Assumptions*, pages 117-118, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- A fiscal year for the ECU Health System (including both ECU Medical Center and SurgiCenter) is from 10/1/___ to 9/30/___.
- The first three project years are FY27, FY28 and FY29.
- The applicant summarized the historical surgical cases from FY18 to FY29 for both ECU Medical Center and SurgiCenter. The historical surgical cases included surgeries performed in ECU Medical Center’s hybrid OR and excluded C-sections performed in dedicated C-section ORs.
- The applicant calculated the average percentage change in surgical cases over Five Years from FY18 to FY23 [Note- FY23 was annualized based on actual internal data through March 2023] for both ECU Medical Center and SurgiCenter:
- The applicant calculated the historical percentages of IP surgical cases and OP surgical cases for ECU Medical Center from FY18 to FY23. The applicant makes note of a shift in the IP/OP split and attributes some of this to the effects of COVID but *“mostly caused by a shift in orthopedic joint cases shift from IP to OP. This is a result of changes in Medicare reimbursement.”* The applicant believes the shift in the IP/OP split towards OP to be permanent and continue into the future.
- For ECU Medical Center, the applicant projected surgical cases for FY24 to FY29 by assuming surgical case volumes will increase at historical (FY2018-FY2023) growth rate in FY2024 and then, to be conservative, trend downward to an average annual growth rate of 1.0% by FY2028 and FY2029, which is equal to the population growth rate.
- For SurgiCenter, the applicant states that SurgiCenter lost significant volume in FY20 due to COVID. Prior to COVID the applicant states that the SurgiCenter averaged 11,700 surgical cases per year. The assumptions and methodology used brings the SurgiCenter back to approximately 11,700 surgical cases per year in FY24 and FY25 and then, conservatively, the applicant assumes an average annual growth rate of 1.0% through the third project year of FY2029, which is equal to the population growth rate.

In Section Q, the applicant calculated OR need for ECU Medical Center and SurgiCenter. As shown in the tables below, without the proposed three additional ORs applied for in this application, the calculations show a need for six additional ORs at ECU Medical Center in each of the first three project years. In addition, the calculations also show a need for three additional ORs at SurgiCenter in each of the first three project years. In total, the ECU Health System projects a need for a total of nine ORs in each of the first three project years.

ECU Medical Center: Projected OR Utilization

Row	Operating Rooms	Year 1 FFY2027	Year 2 FFY2028	Year 3 FFY2029
A	Inpatient Surgical Cases	11,504	11,487	11,469
B	Inpatient Surgical Case Times (in Minutes)	186	186	186
C	Inpatient Surgical Hours	35,664	35,611	35,554
D	Outpatient Surgical Cases	14,642	14,920	15,203
E	Outpatient Surgical Case Times (in Minutes)	131	131	131
F	Outpatient Surgical Hours	31,968	32,575	33,193
G	Total Surgical Cases (Row A + Row D)	26,146	26,408	26,672
H	Total Surgical Hours (Row C + Row F)	67,632	68,187	68,747
I	Group Assignment	1	1	1
J	Standard Hours per OR per Year	1,950	1,950	1,950
K	Number of ORs Needed* (Row H / Row J)	34.68	34.97	35.25
L	Approved OR capacity**	29	29	29
M	OR Surplus/ (Deficit) at ECU Medical Center	(6)	(6)	(6)
N	ORs Applied for in this Application (Q-12392-23)	3	3	3

Source: Section Q, Form C.3b.

Note: Totals might not foot due to rounding.

*Rounding: If 0.50 or higher rounded to the next highest whole number per the 2023 SMFP.

**Number of ORs ECU Medical Center is currently approved for not including ORs which are excluded from the planning inventory (4 C-Section ORs and 1 Trauma/Burn OR). Furthermore, this does not include the three additional ORs applied for in this application.

SurgiCenter: Projected OR Utilization

Row	Operating Rooms	Year 1 FFY2023	Year 2 FFY2024	Year 3 FFY2025
A	Inpatient Surgical Cases	0	0	0
B	Inpatient Surgical Case Times (in Minutes)	0	0	0
C	Inpatient Surgical Hours	0	0	0
D	Outpatient Surgical Cases	11,998	12,118	12,239
E	Outpatient Surgical Case Times (in Minutes)	83	83	83
F	Outpatient Surgical Hours	16,597	16,763	16,931
G	Total Surgical Cases (Row A + Row D)	11,998	12,118	12,239
H	Total Surgical Hours (Row C + Row F)	16,597	16,763	16,931
I	Group Assignment	6	6	6
J	Standard Hours per OR per Year	1,312	1,312	1,312
K	Number of ORs Needed* (Row H / Row J)	12.65	12.78	12.91
L	Approved OR capacity**	10	10	10
M	OR Surplus/ (Deficit) at SurgiCenter	(3)	(3)	(3)
N	ORs Applied for at SurgiCenter in this Application (Q-12392-23)	0	0	0

Source: Section Q, Form C.3b.

Note: Totals might not foot due to rounding.

*Rounding: If 0.50 or higher rounded to the next highest whole number per the 2023 SMFP.

**Number of ORs SurgiCenter is currently approved for.

As shown in the table below, the applicant demonstrates the need for the existing and proposed ORs in the ECU Health System at the end of the third full fiscal year following project completion.

ECU Health System Projected OR Surplus/(Deficit)

ECU Health System Facilities with ORs		Year 1 FFY2027	Year 2 FFY2028	Year 3 FFY2029
ECMC	OR Surplus/ (Deficit)*	(6)	(6)	(6)
SurgiCenter	OR Surplus/ (Deficit)*	(3)	(3)	(3)
SUB-TOTAL	OR Surplus/ (Deficit)*	(9)	(9)	(9)
0.50 rounds up. Less rounds down.		(9)	(9)	(9)
ECMC (Current Application)	Proposed Project- 3 New ORs	3	3	3
TOTAL after Project Completion	OR Surplus/ (Deficit)*	(6)	(6)	(6)

The information is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- The 2023 SMFP includes a need determination for three additional ORs in the Pitt/Greene/Hyde/Tyrell multicounty operating room service area and currently the only

ORs in that service are all part of the ECU Health System. The surgical case volume generated by the ECU Health System thus triggered the OR need determination.

- The applicant’s projections of total inpatient and outpatient surgical case volumes by year at its existing surgical facilities are supported by the historical growth rates of surgical case volumes.
- The applicant projected a return to pre-COVID surgical case volumes at SurgiCenter by the third project year (FY2025).
- The applicant’s projected utilization meets the performance standard promulgated in 10A NCAC 14C .2103(a).

Access to Medically Underserved Groups

In Section C, page 53, the applicant states:

“EHMC has an obligation to accept any eastern NC resident requiring medically necessary treatment. ... ECU Health’s Policy on Patient Rights expressly states ‘[Patients] have the right to treatments without discrimination based on age, ethnicity, race, color, religion, culture, language, national origin, sex, gender identity or expression, sexual orientation, physical or mental disability, socioeconomic status, or source of payment.’”

The applicant provides the estimated percentage for each medically underserved group during the third full fiscal year, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients Surgical Services
Low-income persons*	n/a
Racial and ethnic minorities	44.5%
Women	51.5%
Persons with Disabilities*	n/a
Persons 65 and older	34.4%
Medicare beneficiaries	43.1%
Medicaid recipients	15.6%

Source: Table on page 53 of the application.

*ECU Medical Center does not collect patient level data related to handicapped status or personal income.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID# Q-12397-23/ Eastern Nephrology ASC/ Develop a new ASF with no more than one single specialty dedicated vascular OR and three procedure rooms

The applicant proposes to develop a new ASF with no more than one single specialty dedicated vascular OR and three procedure rooms pursuant to the need determination in the 2023 SMFP. The applicant plans to lease and upfit shell space in a new medical office building.

Patient Origin

N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” On page 47, the 2023 SMFP states, “*An OR’s service area is the single or multicounty grouping shown in Figure 6.1.*” Eastern Nephrology ASC is proposed to be developed in Pitt County. In Figure 6.1, page 53 of the 2023 SMFP, Pitt County is shown as part of the Pitt/Greene/Hyde/Tyrrell multicounty operating room service area. Thus, the operating room service area for this facility consists of Pitt, Greene, Hyde and Tyrrell counties. Facilities may also serve residents of counties not included in the service area.

Eastern Nephrology ASC is not an existing facility. The following tables illustrate projected patient origin for the OR.

Eastern Nephrology ASF: Operating Room- Projected Patient Origin						
County	1st FFY (CY 2026)		2nd FFY (CY 2027)		3rd FFY (CY 2028)	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Pitt	122	19.3%	130	19.3%	137	19.3%
Craven	54	8.5%	57	8.5%	60	8.5%
Edgecombe	46	7.2%	48	7.2%	51	7.2%
Lenoir	41	6.5%	44	6.5%	46	6.5%
Martin	36	5.7%	38	5.7%	41	5.7%
Beaufort	33	5.3%	36	5.3%	38	5.3%
Washington	32	5.0%	34	5.0%	36	5.0%
Bertie	31	4.9%	33	4.9%	35	4.9%
Onslow	30	4.7%	32	4.7%	33	4.7%
Nash	16	2.5%	17	2.5%	18	2.5%
Carteret	7	1.1%	7	1.1%	8	1.1%
Other NC Counties & States*	185	29.3%	197	29.3%	208	29.3%
Total	632	100.0%	671	100.0%	711	100.0%

Source: Section C, page 36.

*Includes all other NC counties and other states, each of which represents less than 1.0% of patient total.

In Section C, page 35, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because they are based on the combined historical patient origin [CY2022] for Vascular Care of Greenville and Vascular Care of New Bern (VCNB) where physicians who will be performing surgical services at the proposed facility currently provide vascular access treatment to ESRD patients and vascular treatment procedures to other patients.

Analysis of Need

In Section C, pages 39-62, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Increasing incidence of Chronic Kidney Disease and of End-Stage Renal Disease (pages 40-42).
- Changes in reimbursement for vascular access services provided in office based labs [OBLs] (pages42-43).
- Better quality, access and cost-effectiveness of vascular access and vascular treatment care in licensed ASF setting (pages 43-48).
- Ambulatory surgery trends and cost-effectiveness of ASFs (pages 48-51).
- Service area demographics (pages 51-62).

The information is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- There is a need determination for three ORs in the Pitt/Greene/Hyde/Tyrrell multicounty operating room service area in the 2023 SMFP. The applicant is applying to develop one of the three ORs in Pitt County in accordance with the OR need determination in the 2023 SMFP.
- The applicant uses a reasonable methodology and reasonable assumptions, including historical data from two existing office-based facilities, Vascular Care of Greenville and Vascular Care of New Bern, to demonstrate the need the population projected to be served has for the proposed ASF.
- The applicant uses clearly cited and reasonable demographic data to identify the population growth and the need the identified population has for the proposed services.
- The applicant cited reasonable data regarding improved access for patients, quality advantages, operational efficiencies and cost savings of the proposed project.

Projected Utilization

Pursuant to 10A NCAC 14C .2103(a), the applicant must demonstrate the need for all existing, approved, and proposed ORs in the health system at the end of the third full fiscal year following project completion, using the Operating Room Need Methodology in the 2023 SMFP. Health system is defined in 10ANCAC 14C .2101 and in Chapter 6 Operating Rooms, page 47 of the 2023 SMFP. Pursuant to the definition of health system the proposed Eastern Nephrology ASC would be the only facility in its health system.

Eastern Nephrology ASC is a proposed new ASF. In Section Q, Form C.3b, page 125, the applicant provides projected surgical case utilization at Eastern Nephrology ASC, as illustrated in the following table.

Eastern Nephrology ASC: Projected OR Cases

Surgical Cases	Year 1 CY 2026	Year 2 CY 2027	Year 3 CY 2028
# of ORs	1	1	1
IP Cases	0	0	0
OP Cases	632	671	711
Total Surgical Cases	632	671	711

In Section Q, Form C *Utilization Projection Methodology and Assumptions* pages 126-133, the applicant provides the assumptions and methodology used to project utilization for Eastern Nephrology ASC, which is summarized below.

Step #1:

- Historical and Projected Outpatient Procedures at Office-Based Vascular Care of Greenville and Vascular Care of New Bern (pages 126-127)
- Projected Facility Utilization at Office-Based Vascular Care of Greenville and Vascular Care of New Bern (pages 128-129).

Step #2: Projected Facility Utilization at Eastern Nephrology ASC [CY2026-2028] (pages 129-131).

Step #3: Projected OR Need for Eastern Nephrology ASC [CY2026-CY2028] (page 132)

Step #4: Projected Procedure Room Procedures at Eastern Nephrology ASC [CY2026-CY2028] (page 133)

As shown in the table below, the applicant demonstrates the need for the proposed OR at Eastern Nephrology ASC at the end of the third full fiscal year following project completion.

Eastern Nephrology ASC: Projected OR Utilization

Row	Operating Rooms	Year 1 CY2026	Year 2 CY2027	Year 3 CY2028
A	Inpatient Surgical Cases	0	0	0
B	Inpatient Surgical Case Times (in Minutes)	0	0	0
C	Inpatient Surgical Hours	0	0	0
D	Outpatient Surgical Cases	632	671	711
E	Outpatient Surgical Case Times (in Minutes)	65.7	65.7	65.7
F	Outpatient Surgical Hours	692	735	779
G	Total Surgical Cases (Row A + Row D)	632	671	711
H	Total Surgical Hours (Row C + Row F)	692	735	779
I	Group Assignment	6	6	6
J	Standard Hours per OR per Year	1,312	1,312	1,312
K	Number of ORs Needed* (Row H / Row J)	0.53	0.56	0.59
L	Existing and Approved ORs**	0	0	0
M	OR Surplus/ (Deficit) * (Row K – Row L)	(1)	(1)	(1)
N	ORs Applied for in this Application	1	1	1

Source: Section Q, Form C.3b, page 125.

Note: Totals might not foot due to rounding.

*Rounding: If 0.50 or higher rounded to the next highest whole number per the 2023 SMFP, page 52.

**Number of ORs Eastern Nephrology ASC is currently approved for.

Projected utilization is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- There is a need determination in the 2023 SMFP for three ORs in the Pitt/Greene/Hyde/Tyrrell multicounty operating room service area. The applicant is proposing to develop one of the three ORs in a new ASF in Pitt County.
- The applicant projected surgical cases and procedure room cases based on historical data projected forward at a reasonable growth rate.
- The applicant’s projected utilization meets the performance standard promulgated in 10A NCAC 14C .2103(a).

Access to Medically Underserved Groups

In Section C.6, pages 66-67, the applicant states,

“All Pitt County residents (plus residents of Greene, Hyde, Tyrell and other counties), including low-income persons, racial and ethnic minorities, women, persons with disabilities, the elderly, Medicare and Medicaid beneficiaries, and other underserved group, will have access to ENAASC, as clinically appropriate. ENAASC is committed to providing services to all persons regardless of race, ethnicity, gender, age, religion, creed, disability, national origin, or ability to pay.”

The applicant provides the estimated percentage for each medically underserved group during the third full fiscal year (CY2028), as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	21.60%
Racial and ethnic minorities	72.90%
Women	48.00%
Persons with Disabilities	10.20%
The elderly	52.10%
Medicare beneficiaries	82.36%
Medicaid recipients	6.23%

Source: Table on page 67 of the application.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.

- The applicant describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [persons with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA
Both Applications

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C
Both Applications

Project ID# Q-12392-23/ ECU Medical Center/ Add three ORs

In Section E, page 62, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintain the Status Quo*- The applicant states that maintaining the status quo would not ensure ECU Medical Center enough operating rooms to meet current and projected patient need, improve patient, staff and physician satisfaction, expand services, contain costs, or increase efficiency. Therefore, the applicant states that this was not the most effective or least costly alternative.
- *Extend the Operating Hours*- The applicant states that ECU Medical Center has extended normal operating hours however, it is not a cost-effective solution. The additional staff needed to support extended hours significantly increases operating expenses. In addition to being cost prohibitive, the extended hours negatively impact staff, physician and patient morale. Therefore, the applicant states that this was not the most effective or least costly alternative.
- *Add operating rooms to ECU Health SurgiCenter*- The applicant state that the SurgiCenter does not have the capability to do either inpatient procedures or as complex surgeries as can be performed at ECU Medical Center. Therefore, the applicant states that this was not the most effective alternative.

- *Add ORs to a surgical office within the service area-* The applicant has outpatient single specialty surgical offices within the Pitt/Greene/Hyde/Tyrell service area and considered adding an operating room to one of these offices. However, this option is limiting in that only one type of patient would be treated, this facility would not be able to provide the full range of surgical services even if additional ORs were added. Therefore, the applicant states that this was not the most effective or least costly alternative.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The proposed project meets the need determination in the 2023 SMFP for three additional operating rooms within the Pitt/Greene/Hyde/Tyrell multi-county OR service area.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

Project ID# Q-12397-23/ Eastern Nephrology ASC/ Develop a new ASF with no more than one single specialty dedicated vascular OR and three procedure rooms

In Section E.2, pages 76-78, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo
- Expand the existing office-based vascular center
- Develop a multi-specialty ASF
- Develop the project in another location

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- Maintain the status quo is a less effective alternative as most ESRD vascular access and non-ESRD vascular treatment procedures are performed in an office setting

whereas an ASF offers a more regulated outpatient setting, allows optimal clinic outcomes and care and provides more dedicated/specialized providers. Further, with respect to these same vascular access procedures being performed in a hospital setting an ASF setting is less costly than a hospital setting.

- Expand the existing office-based vascular center is a less effective alternative as Medicare is the primary payor for ESRD patient services and since 2017 Medicare both pays less for vascular access services in an office setting and, in addition, has reduced Medicare payment for these types of procedures and thus office costs are not being covered. Further, as ESRD cases increase an office setting is less able to handle this increased case load and the increasing complexity of the procedures.
- Develop a multi-specialty ASF is less effective as data demonstrates that patients who receive dialysis vascular access care in a dedicated ESRD-focused facility have better outcomes, including lower costs than patients who receive care at either a hospital or a multi-specialty facility, lower mortality rates, fewer hospitalizations, and fewer infections. In addition, unlike most outpatient surgery patients who have one-time cases scheduled in advance, ESRD patients are chronic and are repeat users of vascular access procedures and often need semi-urgent same day service which lends itself to a dedicated facility being the more efficient option.
- Develop the proposed project in another location outside of Pitt County is a less effective alternative as Greene, Hyde and Tyrell counties are not effective geographic alternatives because of population size and the fact that infrastructure is concentrated in Greenville. Furthermore, locating outside of Greenville in Pitt County would ignore the fact that Greenville is the commercial center of Pitt County with the hub of healthcare infrastructure concentrated in Greenville.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C
Both Applications

Project ID# Q-12392-23/ ECU Medical Center/ Add three ORs

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the total capital cost of the project, as shown in the table below.

Construction Costs	\$5,356,500
Medical Equipment	\$4,518,234
Miscellaneous Costs	\$999,183
Total	\$10,873,917

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant provides an equipment list with estimated costs for the medical, furniture and non-medical costs in Form F.1(a) Assumptions.
- The Vice President of ECU Health Facilities and Properties provided a letter certifying the estimated capital costs for the proposed project. See Exhibit 9.

In Section F.3, pages 66-67, the applicant states there will be no start-up costs or initial operating expenses because ECU Medical Center is an existing hospital.

Availability of Funds

In Section F.2, page 64, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Pitt County Memorial Hospital, Inc.	Total
Loans	\$	\$
Cash and Cash Equivalents, Accumulated reserves or OE *	\$10,873,917	\$10,873,917
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$10,873,917	\$10,873,917

* OE = Owner's Equity

Exhibit 10 contains a letter dated June 7, 2023, from the Chief Financial Officer for ECH Health, parent company to ECU Medical Center, documenting the availability of enough accumulated reserves for the capital needs of the proposed project. Exhibit 11 contains the audited financial statements of ECU Health that show that as of September 30, 2022, ECU Health had \$84 million in cash and cash equivalents and a total net position of \$1.223 billion.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- Exhibit 10 contains a letter from the Chief Financial Officer for ECU Health that documents both the availability and commitment of sufficient funds to finance the proposed project.
- Exhibit 11 contains a copy of ECH Health’s balance sheet as of September 30, 2022, showing adequate funds and revenue necessary to cover the capital costs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

	1st Full Fiscal Year*	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Surgical Cases**	26,146	26,408	26,672
Total Gross Revenues (Charges)	\$1,602,795,098	\$1,659,293,626	\$1,717,783,726
Total Net Revenue	\$482,441,325	\$499,447,381	\$517,052,902
Average Net Revenue per Surgical Case	\$18,452	\$18,913	\$19,386
Total Operating Expenses (Costs)	\$428,755,269	\$445,322,548	\$462,534,005
Average Operating Expense per Surgical Case	\$16,399	\$16,863	\$17,342
Net Income	\$53,686,056	\$54,124,833	\$54,518,897

Source: See Section Q, Form F.2b *Projected Revenues and Net Income upon Project Completion: ECU Health Medical Center IP and OP Surgeries*, page 125 of the application.

*1st Full Fiscal Year: 10/1/2026-9/30/2027

**See Form C.3b for ECU Health Medical Center, page 107. Total Surgical Cases are for ECU Health Medical Center only. Surgical cases from ECU Health SurgiCenter are not included.

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

Project ID# Q-12397-23/ Eastern Nephrology ASC/ Develop a new ASF with no more than one single specialty dedicated vascular OR and three procedure rooms

Capital and Working Capital Costs

In Section Q, Form F.1a, page 134 the applicant projects the total capital cost of the project, as shown in the table below.

Site Costs	\$0
Construction Costs	\$6,352,500
Miscellaneous Costs	\$1,460,008
Total	\$7,812,508

In Section F.1, page 79, Section Q, Form F.1a, pages 134, and in Exhibit F.1, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions.

In Section F.3, page 81, the applicant projects that start-up costs will be \$135,000 and initial operating expenses will be \$545,000 for a total working capital of \$680,000. On pages 81-82, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions.

Availability of Funds

In Section F.2, page 79, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Fresenius Vascular Care Greenville MSO, LLC	Total
Loans	\$7,812,508	\$7,812,508
Cash and Cash Equivalents, Accumulated reserves or OE *	\$	\$
Bonds	\$	\$
Other	\$	\$
Total Financing	\$7,812,508	\$7,812,508

* OE = Owner's Equity

In Section F.3, page 82, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

Sources of Financing for Working Capital: Fresenius Vascular Care Greenville MSO, LLC	Amount
Loans	\$680,000
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$
Lines of credit	\$
Bonds	\$
Total *	\$680,000

The applicants state that the proposed project will be funded through a loan. Exhibit F.2 (Tab 10) contains a letter dated June 12, 2023, from the Senior Vice President and Treasurer of National Medical Care, Inc. confirming that he is authorized to commit to enter into a loan agreement to fund the capital costs and working capital costs of the proposed project up to \$8.5 million. The letter further states that National Medical Care, Inc. is ultimately wholly owned by Fresenius Medical Care AG and Co. (Fresenius). Exhibit F.2 also contains a copy of the quarterly report of Fresenius showing that as of March 31, 2023, Fresenius had Cash and Cash Equivalents of \$1,223,890,000.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

Eastern Nephrology ASC: Operating Room

	1st Full Fiscal Year (CY2026)	2nd Full Fiscal Year (CY2027)	3rd Full Fiscal Year (CY2028)
Total Surgical Cases	632	671	711
Total Gross Revenues (Charges)	\$9,335,407	\$10,117,762	\$10,930,556
Total Net Revenue	\$2,941,494	\$3,188,006	\$3,444,109
Average Net Revenue per Surgical Case	\$4,654	\$4,751	\$4,844
Total Operating Expenses (Costs)	\$1,960,325	\$2,164,987	\$2,307,590
Average Operating Expense per Surgical Case	\$3,102	\$3,227	\$3,246
Net Income	\$981,168	\$1,023,019	\$1,136,529

Source: Section Q, Form F.2b *ENAASC-Operating Room*, page 135.

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C
 Both Applications

N.C.G.S. §131E-176(24a) states: “Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.” On page 47, the 2023 SMFP states, “An OR’s service area is the single or multicounty grouping shown in Figure 6.1.” ECU Medical Center is in Pitt County. In Figure 6.1, page 53 of the 2023 SMFP, Pitt County is shown as part of the Pitt/Greene/Hyde/Tyrrell multicounty operating room service area. Thus, the operating room service area for this facility consists of Pitt, Greene, Hyde and Tyrrell counties. Facilities may also serve residents of counties not included in the service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared ORs located in the Pitt/Greene/Hyde/Tyrrell multicounty operating room service area, and the inpatient and outpatient case volumes for each provider, from Table 6A, page 62, and Table 6b, page 74, of the 2023 SMFP.

Pitt County*	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjustments	IP Surgery Cases	OP Surgery Cases
Vidant Surgi Center**	0	10	0	0	0	0	10,995
Vidant Medical Center**	7	0	26	-5	1	10947	10,218
Total	7	10	26	-5	1***	10,947	21,213

Source: 2023 SMFP

*There are no ORs in Greene, Hyde or Tyrrell counties.

**Vidant Surgi Center is now ECU Health SurgiCenter. Vidant Medical Center is now ECU Health Medical Center.

***Vidant Medical Center (now ECU Health Medical Center) was approved for one OR in Project ID# Q-12189-22. That OR has been developed.

Project ID# Q-12392-23/ ECU Medical Center/ Add three ORs

In G, page 73, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved OR services in Pitt County. The applicant states:

“The proposed project is not designed to address the inadequacy or inability of existing providers. The proposed project is intended to increase capacity, access, and quality of the services provided by EHMC to address current and future demand.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2023 SMFP for three additional ORs in the Pitt/Greene/Hyde/Tyrrell multicounty operating room service area and the applicant proposes to develop three ORs in Pitt County.

- The applicant adequately demonstrates that the proposed three ORs are needed in addition to the existing or approved operating rooms in Pitt County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID# Q-12397-23/ Eastern Nephrology ASC/ Develop a new ASF with no more than one single specialty dedicated vascular OR and three procedure rooms

In Section G.2, page 88, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved OR services in the Pitt/Greene/Hyde/Tyrell multicounty OR service area. The applicant states,

“The proposed project will not result in unnecessary duplication because there is not an ESRD-focused or vascular treatment ASF in the Pitt/Greene/Hyde/Tyrell Operating Room Service Area.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved OR services in the service area for the following reasons:

- There is a need determination in the 2023 SMFP for three ORs in the Pitt/Greene/Hyde/Tyrell multicounty OR service area and the applicant proposes to develop one OR.
- The applicant adequately demonstrates that the proposed OR is needed in addition to the existing or approved ORs in Pitt County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C
Both Applications

Project ID# Q-12392-23/ ECU Medical Center/ Add three ORs

In Section Q, Form H, the applicant provides projected staffing for the proposed services through the first three operating years of the project.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.3b. In Sections H.2 and H.3, pages 75-77, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID# Q-12397-23/ Eastern Nephrology ASC/ Develop a new ASF with no more than one single specialty dedicated vascular OR and three procedure rooms

In Section Q, Form H, the applicant provides projected staffing for the proposed services through the first three operating years of the project.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.3b. In Sections H.2 and H.3, pages 90-93, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C Both Applications

Project ID# Q-12392-23/ ECU Medical Center/ Add three ORs

Ancillary and Support Services

In Section I.1, page 78, the applicant identifies the necessary ancillary and support services for the proposed services. On page 78-79, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the fact that ECU Medical Center is an existing hospital, currently provides all necessary ancillary and support services for its existing surgical services and has the capacity in place to support an additional operating room.

Coordination

In Section I, pages 79-80, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit 12. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- ECU Medical Center is an existing academic teaching hospital which has served Pitt County and eastern North Carolina for years with long-standing relationships with home healthcare and hospice agencies, emergency medical services, social services, referral

hospitals local healthcare providers, pharmacies and long-term care institutions. See Exhibit 12 for a list of facilities with which ECU Medical Center has an official relationship.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

Project ID# Q-12397-23/ Eastern Nephrology ASC/ Develop a new ASF with no more than one single specialty dedicated vascular OR and three procedure rooms

Ancillary and Support Services

In Section I.1, page 94, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 94-95, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I.1.1, I.1.2, I.1.3 and Form H. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I.2, pages 95-96, the applicant describes its proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.2 of the application. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA
Both Applications

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA
Both Applications

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C
Both Applications

Project ID# Q-12392-23/ ECU Medical Center/ Add three ORs

In Section K, page 82, the applicant states that the project involves renovating 1,920 square feet of existing space. Line drawings are provided in Exhibit 7.

On page 83, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit 9.

On page 83, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On pages 83-84 the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

Project ID# Q-12397-23/ Eastern Nephrology ASC/ Develop a new ASF with no more than one single specialty dedicated vascular OR and three procedure rooms

In Section K, page 98, the applicant states that the project involves new construction of 11,300 square feet. The applicant plans to upfit shell space in a new MOB and lease the space. Line drawings are provided in Exhibit K.1.

On pages 98-99 and in Exhibit F.1, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 99, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On pages 99-100, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], 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. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C
ECU Medical Center

NA
Eastern Nephrology ASC

Project ID# Q-12392-23/ ECU Medical Center/ Add three ORs

In Section L, page 86, the applicant provides the historical payor mix during the last FFY (10/1/2021 – 9/30/2022) for ECU Health Medical Center as shown in the table below.

ECU Health Medical Center: Entire Facility

Payor Category	Percent of Total Patients Served
Self-Pay	9.2%
Charity Care*	0.0%
Medicare	33.4%
Medicaid	24.6%
Insurance	30.6%
Workers Compensation	0.4%
TRICARE	1.1%
Other (specify)	0.7%
Total	100.0%

Source: Table on page 86 of the application.

*ECU Medical Center does not have a payer classification for “Charity Care”. Charity care represents the amount of uncollected accounts that are “forgiven” based on special circumstances.

In Section L, page 87, the applicant provides the following comparison.

ECU Medical Center: Entire Facility

	Percentage of Total Patients Served (FY22)	Percentage of the Population of the Service Area [Pitt/Greene/Hyde/Tyrell]
Female	58.0%	51.9%
Male	41.9%	48.1%
Unknown	0.1%	na
64 and Younger	72.3%	85.0%
65 and Older	27.7%	15.0%
American Indian	0.2%	0.8%
Asian	0.5%	1.9%
Black or African American	43.3%	36.3%
Native Hawaiian or Pacific Islander	Included in “Asian”	0.2%
White or Caucasian	48.0%	58.6%
Other Race	7.2%	2.2%
Declined / Unavailable	0.8%	n/a

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's

service area which is medically underserved. Therefore, the application is conforming to this criterion.

Project ID# Q-12397-23/ Eastern Nephrology ASC/ Develop a new ASF with no more than one single specialty dedicated vascular OR and three procedure rooms

Eastern Nephrology ASC is not an existing facility. Therefore, Criterion (13a) is not applicable to this review.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

ECU Medical Center

NA

Eastern Nephrology ASC

Project ID# Q-12392-23/ ECU Medical Center/ Add three ORs

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, paged 88-89, the applicant states:

“As a not-for-profit 501c3 organization, EHMC has an obligation to accept any patient requiring medically necessary treatment. ... EHMC is also bound by the Hill-Burton Community Services obligation to provide equal access to care without discrimination and without regard to race, color, creed, national origin, or source of payment. EHMC has fulfilled its required volume of uncompensated care services in compliance with Hill-Burton regulations.”

In Section L, page 89, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights equal access complaints have been filed against ECU Medical Center.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion.

Project ID# Q-12397-23/ Eastern Nephrology ASC/ Develop a new ASF with no more than one single specialty dedicated vascular OR and three procedure rooms
Eastern Nephrology ASC is not an existing facility. Therefore, Criterion (13b) is not applicable to this review.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C
Both Applications

Project ID# Q-12392-23/ ECU Medical Center/ Add three ORs

In Section L, page 90, the applicant projects the following payor mix for the proposed surgical services during the third full fiscal year (10/1/2028 – 9/30/2029) of operation following completion of the project, as shown in the table below.

ECU Medical Center: Surgical Services

Payor Category	Percent of Total Patients Served
Self-Pay	5.7%
Charity Care*	0.0%
Medicare	43.1%
Medicaid	15.6%
Insurance	32.7%
Workers Compensation	1.0%
TRICARE	1.5%
Other (specify)	0.4%
Total	100.0%

Source: Table on page 90 of the application.

*ECU Medical Center does not have a payer classification for "Charity Care". Charity care represents the amount of uncollected accounts that are "forgiven" based on special circumstances.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 5.7% of total surgical services will be provided to self-pay patients, 43.1% to Medicare patients and 15.6% to Medicaid patients.

On page 90, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant based projected percentages on the historical percentages of the existing surgical services.
- Projected percentages were based on actual FY22 data.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

Project ID# Q-12397-23/ Eastern Nephrology ASC/ Develop a new ASF with no more than one single specialty dedicated vascular OR and three procedure rooms

In Section L.3, page 108, the applicant projects the following payor mix for the proposed operating room during third full fiscal year [CY 2028] of operation following completion of the project, as shown in the table below.

Payor Category	Percentage of Total Patients Served
Self-Pay	0.8%
Medicare *	88.1%
Medicaid *	4.9%
Insurance *	6.2%
Total	100.0%

Source: Table on page 108 of the application.

* Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.8% of total services will be provided to self-pay patients, 88.1% to Medicare patients and 4.9% to Medicaid patients.

On page 107, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical CY2022 payor mix for Vascular Care of Greenville and VCNB, which includes the physicians who are projected to utilize the proposed facility.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

Both Applications

Project ID# Q-12392-23/ ECU Medical Center/ Add three ORs

In Section L, page 92, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion.

Project ID# Q-12397-23/ Eastern Nephrology ASC/ Develop a new ASF with no more than one single specialty dedicated vascular OR and three procedure rooms

In Section L.5, pages 109-110, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

Both Applications

Both Applications. In Section M, the applicants describe the extent to which health professional training programs in the area have or will have access to the facility for training purposes and provide supporting documentation in the referenced exhibits.

The Agency reviewed the:

- Applications
- Exhibits to the applications

Based on that review, the Agency concludes that all of the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, all of the applications are conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C Both Applications

N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” On page 47, the 2023 SMFP states, “*An OR’s service area is the single or multicounty grouping shown in Figure 6.1.*” ECU Medical Center is in Pitt County. In Figure 6.1, page 53 of the 2023 SMFP, Pitt County is shown as part of the Pitt/Greene/Hyde/Tyrrell multicounty operating room service area. Thus, the operating room service area for this facility consists of Pitt, Greene, Hyde and Tyrrell counties. Facilities may also serve residents of counties not included in the service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared ORs located in the Pitt/Greene/Hyde/Tyrrell multicounty operating room service area, and the inpatient and outpatient case volumes for each provider, from Table 6A, page 62, and Table 6b, page 74, of the 2023 SMFP.

Pitt County*	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjustments	IP Surgery Cases	OP Surgery Cases
Vidant Surgi Center**	0	10	0	0	0	0	10,995
Vidant Medical Center**	7	0	26	-5	1	10947	10,218
Total	7	10	26	-5	1***	10,947	21,213

Source: 2023 SMFP

*There are no ORs in Greene, Hyde or Tyrell counties.

**Vidant Surgi Center is now ECU Health SurgiCenter. Vidant Medical Center is now ECU Health Medical Center.

***Vidant Medical Center (now ECU Health Medical Center) was approved for one OR in Project ID# Q-12189-22. That OR has been developed.

Project ID# Q-12392-23/ ECU Medical Center/ Add three ORs

Regarding the expected effects of the proposal on competition in the service area, in Section N, pages 95-96, the applicant states:

“The proposed project will foster competition... EHMC’s mission is to improve the health status of the region. EHMC is dedicated to offering needed surgical services to anyone in the community, especially the medically underserved populations....Because of all this, the proposed project will improve quality, reduce patient costs and increase patient access to the latest advancements in surgical services.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 95, the applicant states:

“EHMC will use the proposed new operating rooms to enhance the operational efficiency of surgical services and to increase patient access. These efforts will contain costs and improve access to surgical services.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 95, the applicant states:

“EHMC will use the experience it has in providing surgical services to provide the highest quality services to its patients. ... EHMC’s comprehensive quality assurance program ensures continuation of a high standard of care for all people in the service area. ... EHMC will also use the advanced capabilities of the proposed new operating room to enhance the quality of surgical services... As the only tertiary medical center in eastern NC, EHMC offers additional support and ancillary services on-site and provides care to complex patients.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 95, the applicant states:

“EHMC’s mission is to improve the health status of the region. EHMC is dedicated to offering needed surgical services to anyone in the community, especially the medically

underserved populations. EHMC will use the proposed additional operating rooms to assure services are available to all members of the community – particularly the medically underserved.”

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

Project ID# Q-12397-23/ Eastern Nephrology ASC/ Develop a new ASF with no more than one single specialty dedicated vascular OR and three procedure rooms

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 112, the applicant states:

“The Greenville ASF will enhance competition in the service area because the project will enable interventional nephrologists, interventional radiologists and vascular surgeons to better meet the needs of the existing vascular access patient population, and to ensure timely provision of and convenient access to high quality, cost-effective outpatient surgical services for residents of Pitt County and eastern North Carolina.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 113, the applicant states:

“Currently, there are no licensed ASFs that specialize in vascular access services for ESRD patients in the service area... This OR project will make lower cost vascular access surgery more broadly available to credentialed surgeons and their patients. ENAASC will be a lower charge, lower reimbursement licensed facility.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 115, the applicant states:

“ENAASC will be dedicated to ensuring quality care and patient safety through compliance with all applicable licensure and certification standards established for ambulatory surgical facilities.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 116, the applicant states:

“ENAAAC is committed to providing services to all persons, regardless of race, ethnicity, gender, age, religion, creed, disability, national origin, or ability to pay, as demonstrated in the non-discrimination policies provide in Exhibit C.6.”

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C
Both Applications

Project ID# Q-12392-23/ ECU Medical Center/ Add three ORs

In Section Q, Form O, page 135, the applicant identifies nine hospitals located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O, page 99, the applicant states that, during the 18 months immediately preceding the submittal of the application, *“None of the facilities ...were determined by the Division of Health Service Regulation to have had any situations resulting in a finding of immediate jeopardy during the 18 month look-back period.”* According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to immediate jeopardy occurred in none of the nine facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all nine facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID# Q-12397-23/ Eastern Nephrology ASC/ Develop a new ASF with no more than one single specialty dedicated vascular OR and three procedure rooms

In Section Q, Form O, page 144, the applicant identifies two ambulatory surgical facilities located in North Carolina owned, operated, or managed by the applicant or a related entity.

In Section O.5, page 125, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents resulting in a finding of immediate jeopardy occurred in either of these facilities. According to the files in the Acute and Home Care Licensure Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure Section and considering the quality of care provided at both facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183(b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

Both Applications

SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

10A NCAC 14C .2103 PERFORMANCE STANDARDS

(a) *An applicant proposing to increase the number of operating rooms, excluding dedicated C-section operating rooms, in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the annual State Medical Facilities Plan. The applicant is not required to use the population growth factor.*

-C- ECU Medical Center. This proposal would develop three additional ORs at an existing hospital. The service area is the Pitt/Greene/Hyde/Tyrell multicounty operating room service area. There are no ORs in Greene, Hyde or Tyrell counties. The only two facilities with ORs in Pitt County are ECU Medical Center and SurgiCenter. ECU Medical Center and SurgiCenter are separately licensed, however, they are related entities. In Section Q, the applicant projects sufficient surgical cases and hours to demonstrate the need for three additional OR in the applicant's health system in the third operating year of the project based on the Operating Room Need Methodology in the 2023 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

-C- Eastern Nephrology ASC. This proposal would develop a new ASF with one single specialty dedicated vascular OR and three procedure rooms. The service area is the Pitt/Greene/Hyde/Tyrell multicounty operating room service area. There are no ORs in Greene, Hyde or Tyrell counties. The applicant is not part of any health system with any existing or approved ORs in the Pitt/Greene/Hyde/Tyrell multicounty operating room service area. In Section Q, the applicant projects sufficient surgical cases and hours to demonstrate the need for one OR in the third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology

in the 2023 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (b) *The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.*
- C- ECU Medical Center.** In Section Q, Form C, pages 103-118, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.
- C- Eastern Nephrology ASC.** In Section Q, Form C *Utilization Projection Methodology and Assumptions*, Form C.3b, pages 125-133, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

COMPARATIVE ANALYSIS FOR OPERATING ROOMS

Pursuant to G.S. 131E-183(a)(1) and the 2023 SMFP, no more than three operating rooms may be approved for the Pitt/Greene/Hyde/Tyrell service area in this review. Because the two applications in this review are applying collectively propose to develop four additional operating rooms, both the applications cannot be approved as proposed. Therefore, after considering all the information in both applications and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposals should be approved.

Because of the significant differences in types of facilities, numbers of total ORs, numbers of projected surgeries, types of proposed surgical services offered, total revenues and expenses, and the differences in presentation of pro forma financial statements, some comparatives may be of less value and result in less than definitive outcomes than if all applications were for like facilities of like size proposing like services and reporting in like formats.

Further, the analysis of comparative factors and what conclusions the Agency reaches (if any) with regard to specific comparative analysis factors is determined in part by whether or not the applications included in the review provide data that can be compared and whether or not such a comparison would be of value in evaluating the competitive applications.

Below is a brief description of each project included in the Comparative Analysis:

- Project ID # Q-12392-23/ **ECU Health Medical Center/ Develop 3 ORs**

- Project ID # Q-12397-23/ **Eastern Nephrology Associates ASC**/ Develop a new ASC with no more than one single specialty dedicated vascular OR and three procedure rooms

Conformity with Statutory and Regulatory Review Criteria

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved. Both applications are conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, both applications are equally effective alternatives.

Scope of Services

Generally, the application proposing to provide the greatest scope of services is the more effective alternative with regard to this comparative factor.

ECU Medical Center is an acute care hospital which provides numerous types of surgical services, both inpatient and outpatient in a hospital.

Eastern Nephrology ASC is a proposed single specialty dedicated vascular ASF that will provide outpatient surgical services only in an ambulatory surgical facility.

Therefore, ECU Medical Center is the more effective alternative with respect to this comparative factor and Eastern Nephrology ASC is less effective.

Geographic Accessibility

The 2023 SMFP identifies the need for three ORs in the Pitt/Greene/Hyde/Tyrrell multicounty OR service area.

The following table illustrates where in the service area each applicant proposes to develop its proposal.

	Proposed Locations
ECU Medical Center	2100 Stantonsburg Road, Greenville
Eastern Nephrology ASC	2300 Emerald Place, Greenville

Both applications are proposing to locate in Greenville. Per Google Maps the two locations are approximately 1.4 miles apart (5 min drive).

Thus, with respect to geographic accessibility, the applications of ECU Medical Center and Eastern Nephrology ASC are equally effective alternatives.

Patient Access to Lower Cost Surgical Services

ORs can be licensed as part of a hospital or an ASF. Based on the applications, written comments, and response to comments, 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 higher if performed in a hospital-based OR or, conversely, 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 outpatient surgery cases are appropriate for an OR located at an ASF and even though some outpatient surgery must be performed in a hospital based OR, all inpatient surgical services must be performed in a hospital-based OR.

ECU Medical Center is an existing acute care hospital which provides numerous types of OR surgical services, both inpatient and outpatient.

Eastern Nephrology ASC is a proposed single specialty dedicated vascular ASF that will provide OR outpatient surgical services only in an ambulatory surgical facility [not operating under a hospital license].

Therefore, as to patient access to lower cost outpatient OR surgical services the application submitted by Eastern Nephrology ASC is the more effective alternative with respect to this comparative factor and the application submitted by ECU Medical Center is less effective.

Historical Utilization

Generally, applications proposing to develop additional operating rooms in the health systems with the highest projected operating room deficits are the more effective alternative with regard to this comparative factor.

ECU Medical Center is an existing facility. ECU Medical Center is also part of an existing health system in the Pitt/Greene/Hyde/Tyrrell multicounty OR service area.

Eastern Nephrology ASF is a proposed new ASF with no historical utilization. In addition, Eastern Nephrology ASF is not part of any existing health system in the Pitt/Greene/Hyde/Tyrrell multicounty OR service area.

Therefore, a comparison of historical utilization cannot be effectively evaluated.

Competition (Patient Access to a New or Alternative Provider)

Generally, the introduction of a new provider in the service area would be the more effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, the expansion of an existing provider that currently controls fewer operating rooms than another provider would also presumably encourage all providers in the service area to improve quality or lower costs in order to compete for patients.

N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” On page 47, the 2023 SMFP states, “*An OR’s service area is the single or multicounty grouping shown in Figure 6.1.*” Both the facilities in this review are in, or proposed for, Pitt County. In Figure 6.1, page 53 of the 2023 SMFP, Pitt County is shown as part of the Pitt/Greene/Hyde/Tyrrell multicounty operating room service area. Thus, the operating room service area for both facilities in this review consists of Pitt, Greene, Hyde and Tyrrell counties. Facilities may also serve residents of counties not included in the service area.

ECU Medical Center currently provides OR services in the Pitt/Greene/Hyde/Tyrrell County multicounty OR service area. County. Eastern Nephrology ASC is a new facility and is not part of a health system that provides OR services and does not currently provide OR services in the Pitt/Greene/Hyde/Tyrrell multicounty OR service area.

Therefore, Eastern Nephrology ASC would qualify as a new or alternative provider in the service area. Therefore, regarding this comparative factor, the application submitted by Eastern Nephrology ASC is the more effective alternative and the application of ECU Medical Center is the less effective alternative with respect to this comparative factor.

Access by Service Area Residents

N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” On page 47, the 2023 SMFP states, “*An OR’s service area is the single or multicounty grouping shown in Figure 6.1.*” Both the facilities in this review are in, or proposed for, Pitt County. In Figure 6.1, page 53 of the 2023 SMFP, Pitt County is shown as part of the Pitt/Greene/Hyde/Tyrrell multicounty operating room service area. Thus, the operating room service area for both facilities in this review consists of Pitt, Greene, Hyde and Tyrrell counties. Facilities may also serve residents of counties not included in the service area.

Generally, the application projecting to serve the highest percentage of residents from Pitt/Green/Hyde/Tyrrell counties is the more effective alternative with regard to this comparative factor since the need determination is for three additional operating rooms to be located in the Pitt/Green/Hyde/Tyrrell county OR service area.

3rd Full FY

Applicant	# of Pitt/Green/Hyde/Tyrell Patients	Total Patients	% of Pitt/Green/Hyde/Tyrell County Patients
ECU Medical Center	9,262*	26,672	34.73%
Eastern Nephrology ASC	137*	711	19.27%

Source: Section C.3 both applications.

*Total of Pitt and Greene County lines from Table on page 36. The table contained no individual lines for either Hyde or Tyrell county.

*Total from Pitt County line from Table on page 36. The table contained no individual lines for Greene, Hyde or Tyrell counties.

With regard to this comparative factor the application of ECU Medical Center is the more effective alternative and the application of Eastern Nephrology ASC is less effective.

Access by 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.”

Projected Medicare

The following table shows each applicant’s percentage of gross revenue (charges) projected to be provided to Medicare patients in the applicant’s third full year of operation following completion of their projects, based on the information provided in the applicant’s pro forma financial statements in Section Q. Generally, the application proposing to provide a higher percentage of services to Medicare patients is the more effective alternative with regard to this comparative factor.

Services to Medicare Patients: Operating Rooms - Project Year 3

Applicant	Medicare Gross Revenue	Total Gross Revenue	Medicare % of Total Gross Revenue
ECU Medical Center	\$815,410,341	\$1,717,783,726	47.47%
Eastern Nephrology ASC	\$9,629,820	\$10,939,556	88.03%

Source: Form F.2 for each applicant.

With regard to this comparative factor Eastern Nephrology ASF projects the higher percentage of Medicare as part of Total Gross Revenue and therefore is the more effective alternative.

However, the differences in the acuity level of patients at each facility, the level of care (tertiary care hospital and single specialty ASF) 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. Thus, the result of this analysis is inconclusive.

Projected Medicaid

The following table shows each applicant’s percentage of gross revenue (charges) projected to be provided to Medicaid patients in the applicant’s third full year of operation following completion of their projects, based on the information provided in the applicant’s pro forma financial statements in Section Q. Generally, the application proposing to provide a higher percentage of services to Medicaid patients is the more effective alternative with regard to this comparative factor.

Services to Medicaid Patients: Operating Rooms Only - Project Year 3

	Medicaid Gross Revenue	Total Gross Revenue	Medicaid % of Total Gross Revenue
ECU Medical Center	\$281,844,591	\$1,717,783,726	16.4%
Eastern Nephrology ASC	\$535,597	\$10,939,556	4.9%

Source: Form F.2 for each applicant.

With regard to this comparative factor ECU Medical Center projects the higher percentage of Medicaid as part of Total Gross Revenue and therefore is the more effective alternative.

However, the differences in the acuity level of patients at each facility, the level of care (tertiary care hospital and single specialty ASF) 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. Thus, the result of this analysis is inconclusive.

Projected Average Net Revenue per Case

The following table shows the projected average net 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 since a lower average may indicate a lower cost to the patient or third-party payor.

Net Revenue per Surgical Case - Project Year 3

	Net Revenue	# of Cases	Net Revenue/Case
ECU Medical Center	\$517,052,902	26,672*	\$19,386
Eastern Nephrology ASC	\$3,444,109	711	\$4,844

Source: Form F.2 for each application.

*Note: the number of surgical cases does not include C-Sections performed in dedicated C-Section ORs.

With regard to this comparative factor Eastern Nephrology ASF projects a lower net revenue per surgical case and therefore is the more effective alternative.

However, the differences in the acuity level of patients at each facility, the level of care (tertiary care hospital and single specialty ASF) 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. Thus, the result of this analysis is inconclusive.

Projected Average Operating Expense per Case

The following table shows the projected average operating expense per patient 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 since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

Operating Expense per Surgical Case - Project Year 3

	Operating Expense	# of Surgical Cases	Operating Expense per Surgical Case
ECU Medical Center	\$462,534,005	26,672*	\$17,342
Eastern Nephrology ASC	\$2,307,590	711	\$3,246

Source: Forms F.2 in each application.

*Note: the number of surgical cases does not include C-Sections performed in dedicated C-Section ORs.

With regard to this comparative factor Eastern Nephrology ASF projects a lower operating expense per surgical case and therefore is the more effective alternative.

However, the differences in the acuity level of patients at each facility, the level of care (tertiary care hospital and single specialty ASF) 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. Thus, the result of this analysis is inconclusive.

SUMMARY

The following table lists the comparative factors and states which application is the more effective alternative with regard to that particular comparative factor. Note: the comparative factors are listed in the same order they are discussed in the Comparative Analysis, which should not be construed to indicate an order of importance.

Comparative Factor	ECU Medical Center	Eastern Nephrology ASC
Conformity with Review Criteria	Equally Effective	Equally Effective
Scope of Services	More Effective	Less Effective
Geographic Accessibility	Equally Effective	Equally Effective
Patient Access to Lower Cost Surgical Services	Less Effective	More Effective
Historical Utilization	Inconclusive	Inconclusive
Competition [Access to New or Alternate Provider]	Less Effective	More Effective
Access by Service Area Residents	More Effective	Less Effective
Projected Medicare	Inconclusive	Inconclusive
Projected Medicaid	Inconclusive	Inconclusive
Projected Average Net Revenue per Case	Inconclusive	Inconclusive
Projected Average Operating Expense per Case	Inconclusive	Inconclusive

- With respect to Conformity with Review Criteria, both applications are equally effective alternatives. See Comparative Analysis for discussion.

- With respect to Scope of Services, **ECU Medical Center** is the more effective alternative. See Comparative Analysis for discussion.
- With respect to Geographic Accessibility, both applications are equally effective alternatives. See Comparative Analysis for discussion.
- With respect to Patient Access to Low-Cost Surgical Services, **Eastern Nephrology ASC** is the more effective alternative. See Comparative Analysis for discussion.
- With respect to Competition/Access to New or Alternate Provider, **Eastern Nephrology ASC** is the more effective alternative. See Comparative Analysis for discussion.
- With respect to Patient Access to Lower Cost Surgical Services, **ECU Medical Center** is the more effective alternative. See Comparative Analysis for discussion.

DECISION

Each of the two applications is individually conforming to the need determination in the 2023 SMFP for three ORs in the Pitt/Greene/Hyde/Tyrrell multicounty operating room service area. However, G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of ORs that can be approved by the Healthcare Planning and Certificate of Need Section.

After the initial comparative review both applications were determined to be the more effective as to two comparative factors.

The application for ECU Medical Center seeks to develop three additional ORs at ECU Medical Center. The application for Eastern ASF seeks to develop one OR as part of a new single specialty dedicated vascular ASF.

There are only three ORs available in the 2023 SMFP OR need determination for the Pitt/Greene/Hyde/Tyrrell multicounty operating room service area. As Eastern ASF only applied to develop one new OR two of the three ORs are conditionally approved for ECU Medical Center. However, that still leaves one OR to be approved.

The applications for ECU Medical Center and Eastern Nephrology ASC were both found to be the more effective alternative for two comparative factors and equally effective for two comparative factors.

However, in the Pitt/Greene/Hyde/Tyrrell multicounty OR service area, the applicant (Pitt County Memorial Hospital, Inc.) that submitted the ECU Medical Center application, as discussed above, currently has 29 ORs (excluding dedicated C-Section ORs and 1 Trauma/Burn OR) located at ECU Medical Center plus the SurgiCenter (a related entity) has 10 ORs for a combined total of 39 ORs in the ECU Health System (excluding dedicated C-Section ORs and 1 Trauma/Burn OR at ECU Medical Center), while the applicants (Eastern Nephrology Associates ASC, LLC and Fresenius Vascular Care Greenville MSO, LLC) that submitted the Eastern Nephrology ASC application do not own any ORs nor are they part of a Health System in the service area that has any ORs. Therefore, based on the

benefits of competition discussed above in the comparative factor *Competition (Patient Access to New or Alternative Provider)* and the total number of ORs owned by Pitt County Memorial Hospital, Inc. as compared to Eastern Nephrology Associates ASC, LLC and Fresenius Vascular Care Greenville MSO, LLC, the application of Eastern Nephrology ASC [Project ID# Q-12397-23] is conditionally approved and the application for ECU Medical Center is conditionally approved as is modified in the description below:

Based upon the independent review of each application and the Comparative Analysis, the following application is conditionally approved as modified in the description below:

- Project ID# Q-12392-23/ **ECU Medical Center**/ Develop no more than two ORs pursuant to the 2023 SMFP need determination for a total of 36 ORs, including 4 dedicated C-Section ORs and 1 Trauma OR

Based upon the independent review of each application and the Comparative Analysis, the following application is conditionally approved as submitted:

- Project ID# Q-12397-23/ **Eastern Nephrology Associates ASC** / Develop a new ASF with no more than one single specialty dedicated vascular OR pursuant to the 2023 SMFP need determination and three procedure rooms

Project ID# Q-12392-23/ ECU Medical Center, is approved subject to the following conditions.

1. **Pitt County Memorial Hospital, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holder shall develop no more than two ORs pursuant to the 2023 SMFP need determination for a total of no more than 31 ORs at ECU Medical Center (excluding four C-Section operating rooms and one Trauma/Burn OR) upon project completion.**
3. **Upon completion of the project, ECU Health Medical Center shall be licensed for no more than 36 operating rooms (31 operating rooms, four C-Section operating rooms and one trauma/burn operating room).**
4. **Progress Reports:**
 - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. **The certificate holder shall complete all sections of the Progress Report form.**

- c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. The first progress report shall be due on March 1, 2024.
5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
6. The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.
7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

Project ID# Q-12397-23/ Eastern Nephrology Associates ASC, is approved subject to the following conditions.

1. Eastern Nephrology Associates, LLC and Fresenius Vascular Care Greenville MSO, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
2. The certificate holder shall develop no more than one single specialty dedicated vascular OR pursuant to the 2023 SMFP need determination for a total of no more than one OR upon project completion.
3. Upon completion of the project, Eastern Nephrology Associates ASC shall be licensed for no more than one operating room.
4. Progress Reports:
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
 - b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. The first progress report shall be due on July 1, 2024.

- 5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 6. The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
- 7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**