

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: November 16, 2023

Findings Date: November 16, 2023

Project Analyst: Julie M. Faenza

Co-signer: Gloria C. Hale

Project ID #: F-12423-23

Facility: Vascular ASC

FID #: 230722

County: Iredell

Applicant: Vascular, PLLC

Project: Develop a new ASF with no more than one dedicated vascular access OR pursuant to the need determination in the 2023 SMFP

### 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.

NC

Vascular, PLLC (hereinafter referred to as “the applicant”) proposes to develop a new dedicated vascular access ambulatory surgical facility (ASF), Vascular ASC, by developing one operating room (OR) pursuant to a need determination for Health Service Area (HSA) III.

#### **Need Determination**

Chapter 6 of the 2023 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional ORs in North Carolina by service area. Application of the need methodology in the 2023 SMFP did not result in a need determination for any ORs in any of the counties that are contained within HSA III. However, pursuant to a petition submitted to the State Health Coordinating Council (SHCC) and the SHCC’s subsequent

approval, Chapter 6 of the 2023 SMFP contains an adjusted need determination for one dedicated vascular access OR in each of the six HSAs in North Carolina.

The applicant does not propose to develop more ORs than are approved to be developed by the SMFP and proposes to develop a dedicated vascular access OR. The applicant proposes to develop the ASF in Iredell County, which is one of the counties within HSA III. Therefore, the application is consistent with the need determination in the 2023 SMFP.

### **Policies**

There is one policy in the 2023 SMFP which is applicable to this review. *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.”*

In Section B, pages 27-28, the applicant explains why it believes its application is consistent with Policy GEN-3.

However, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximizing healthcare value for resources expended. The applicant does not adequately demonstrate the need to develop the new ASF and does not adequately demonstrate that developing the new ASF would not be an unnecessary duplication of existing and approved services. The discussions regarding need (and projected utilization) and unnecessary duplication found in Criterion (3) and Criterion (6), respectively, are incorporated herein by reference. An applicant that does not demonstrate the need for the proposed project, does not demonstrate that projected utilization is reasonable and adequately supported, and does not demonstrate that the proposed project is not an unnecessary duplication of existing and approved health care services in the service area cannot demonstrate that it will maximize healthcare value for resources expended in meeting the need identified in the 2023 SMFP. Therefore, the application is not consistent with Policy GEN-3.

### **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 not conforming to this criterion based on the following:

- The applicant does not adequately demonstrate the need to develop a new ASF or that developing a new ASF would not be an unnecessary duplication of existing and approved health care services.
  - Therefore, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum healthcare value for resources expended as required in Policy GEN-3.
- (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.

NC

The applicant proposes to develop a new dedicated vascular access ASF, Vascular ASC, by developing one OR pursuant to the adjusted need determination for HSA III in the 2023 SMFP. The new ASF would be located in Statesville in Iredell County.

### **Patient Origin**

On page 47, the 2023 SMFP defines the service area for ORs as “...*the single or multicounty grouping shown in Figure 6.1.*” Figure 6.1 on page 53 of the 2023 SMFP shows Iredell County as its own OR service area; however, pursuant to the adjusted need determination on page 79 of the 2023 SMFP, the service area for this project is HSA III. Facilities may also serve residents of counties not included in their service area.

Vascular ASC is not an existing facility. The following table shows projected patient origin for the first three full fiscal years following project completion.

<b>Vascular ASC Projected Patient Origin – FYs 1-3 (FFYs* 2026-2028)</b>						
<b>HSA</b>	<b>FY 1 (FFY* 2026)</b>		<b>FY 2 (FFY* 2027)</b>		<b>FY 3 (FFY* 2028)</b>	
	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
HSA III	352	75.1%	469	75.1%	469	75.1%
HSA I**	113	24.1%	150	24.1%	150	24.1%
HSA II***	4	0.8%	5	0.8%	5	0.8%
<b>Total</b>	<b>468</b>	<b>100.0%</b>	<b>624</b>	<b>100.0%</b>	<b>624</b>	<b>100.0%</b>

Source: Section C, page 38

\*FFYs = Federal Fiscal Years (October 1 – September 30)

\*\*Includes only Alexander, Catawba, and Wilkes counties

\*\*\*Includes only Davie and Yadkin counties

In Section C, page 39, the applicant provides the assumptions and methodology used to project patient origin. The applicant projects patient origin based on a 30-mile radius of the location of the proposed facility. Projected patient origin is reasonable and adequately supported based on the following:

- The applicant relied on the experience of local nephrologists regarding where their patients reside.
- The applicant excludes counties located in HSA III if they are outside of the 30-mile radius.

**Analysis of Need**

In Section C, pages 41-54, the applicant explains why the patients it proposes to serve need the proposed services, as summarized below.

- Advances in understanding the causes of kidney disease and which treatments are most effective, as well as efforts from government organizations to increase treatment options for kidney disease patients means more patients will be accessing dialysis, including home treatment options and transplants. The most optimal patient treatment options begin with permanent vascular access that will be provided by the applicant. (pages 41-43)
- Kidney disease is caused by and aggravated by multiple comorbidities, lifestyle choices, and other factors related to community health. The counties in the proposed area of patient origin have higher rates of diseases and/or higher rates of risk factors from lifestyle choices in multiple categories than the statewide average for North Carolina. (pages 43-49)
- There is an adjusted need determination for a dedicated vascular access ASF in HSA III. (page 49)
- Multiple physicians have supported the proposed project and provided letters of support included in the application. (page 50)

- The population for people aged 65 and older in HSA III has grown by 22.1% over the last five years. The North Carolina Office of State Budget and Management projects further growth between 2023 and 2028, and projects the population aged 65 and older will increase at rates much higher than other age cohorts. The applicant states that people aged 65 and older will account for approximately 85% of vascular access cases at Vascular ASC. (pages 51-52)
- A number of public sources and government entities have published articles and other documents indicating there are a number of factors that impact treatment for patients with kidney disease and which support the need for a vascular access OR. (pages 53-54)

The information is reasonable and adequately supported for the following reasons:

- The applicant cites numerous sources from medical and government entities that support the applicant’s statements about treatment options for kidney disease patients and which support the need for more options for vascular access.
- The applicant provides reliable data, makes reasonable statements about the data, and uses reasonable assumptions about the data to demonstrate the projected population growth in the area and the projected growth of the population age 65 and older in the area.

Projected Utilization

On Form C.3b in Section Q, the applicant projects utilization for the first three full fiscal years of operation following project completion, as shown in the table below.

<b>Vascular ASC Projected Utilization – FYs 1 – 3 (FFYs 2026 – 2028)</b>			
	<b>FY 1 (FFY 2026)</b>	<b>FY 2 (FFY 2027)</b>	<b>FY 3 (FFY 2028)</b>
ORs	1	1	1
Outpatient Surgical Cases	983	1,311	1,311
Outpatient Case Times (hours)	1.10	1.10	1.10
Total Surgical Hours	1,081	1,442	1,442
Standard Hours per OR per Year (Group 6)	1,312	1,312	1,312
# of ORs Needed*	0.82	1.10	1.10

\*Number of ORs Needed = Total Surgical Hours / Standard Surgical Hours per OR per Year (Group 6)

In the Utilization Methodology and Assumptions subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, as summarized below.

- The applicant identified the counties located within the 30-mile radius of the proposed facility, used publicly available data to determine the number of home peritoneal dialysis patients and in-center dialysis patients in each county for each year between 2020 and 2022, and calculated a three-year average number of home peritoneal dialysis patients and in-center dialysis patients for each HSA (based on the counties within each HSA that fell within the 30-mile travel radius).

- The applicant projects that 10% of home peritoneal dialysis (PD) patients will require vascular access because they will transition to in-center (IC) patients, and states that 100% of in-center dialysis patients will need vascular access. The applicant projects the number of dialysis patients who will need vascular access for each HSA by applying those percentages to the respective average number of PD and IC patients based on the three-year average of those patients previously calculated.
- The applicant projects that it will serve 15% of HSA III patients, 30% of HSA I patients, and 3.75% of HSA II patients in its first full fiscal year following project completion. The applicant projects it will serve 20% of HSA III patients, 40% of HSA I patients, and 5% of HSA II patients during the second and third full fiscal years following project completion.
- The applicant states the assumptions of patients to be served are based on the following factors:
  - There is an existing vascular access ASF in HSA III;
  - There was no applicant for a dedicated vascular access ASF pursuant to the adjusted need determination in HSA I; and
  - There was one applicant for a dedicated vascular access ASF pursuant to the adjusted need determination in HSA II.
- The applicant projected the number of vascular access cases by using referring nephrologist data. The applicant states the number of vascular access cases averages between 1.8 cases and 2.4 cases per patient per year; the applicant projects each patient will need 2.1 vascular access cases per year and uses that figure to calculate the total number of vascular access cases each year.
- The applicant used the standard case time for Group 6 facilities to project total OR hours.

The applicant's assumptions and methodology used to project utilization are summarized in the table below.

<b>Vascular ASC Projected Utilization</b>			
	<b>FFY 2026</b>	<b>FFY 2027</b>	<b>FFY 2028</b>
HSA I Average # of Dialysis Patients Needing Vascular Access	375	375	375
HSA I Projected Market Capture	30.00%	40.00%	40.00%
HSA I Projected Vascular Access Patients	113	150	150
HSA II Average # of Dialysis Patients Needing Vascular Access	104	104	104
HSA II Projected Market Capture	3.75%	5.00%	5.00%
HSA II Projected Vascular Access Patients	4	5	5
HSA III Average # of Dialysis Patients Needing Vascular Access	2,344	2,344	2,344
HSA III Projected Market Capture	15.00%	20.00%	20.00%
HSA III Projected Vascular Access Patients	352	469	469
Total Projected Vascular Access Patients	469	624	624
Average # of Vascular Access Cases per Patient per Year	2.1	2.1	2.1
Projected # of Vascular Access Cases	983	1,311	1,311
Projected Hours per Case (Group 6)	1.10	1.10	1.10
Total Surgical Hours	1,081	1,442	1,442
Total Surgical Hours – Group 6	1,312	1,312	1,312
ORs Needed	0.82	1.10	1.10

However, projected utilization is not reasonable and adequately supported based on the following:

- The applicant does not adequately explain why it believes the existence of dedicated vascular access ASFs (or lack of vascular access ASFs) is related to the number of dialysis patients it will serve at its proposed facility and does not provide documentation that supports the percentages and numbers of dialysis patients it projects to serve in each HSA for each fiscal year of the proposed project. Further, the applicant provides no support for the assumption that projected patients will choose the proposed facility for vascular access at the numbers they propose when there are other providers, such as hospitals and ASFs in the HSA, who currently provide the services proposed.
- In Section C, page 50, the applicant states that it has documented up to 300 patient referrals from local nephrologists. In Exhibit C.4, the applicant provides letters of support from local nephrologists, but only one contains projections about patients to be referred; the others state the total number of kidney disease patients they serve but do not indicate how many will need vascular access services, and one letter states “many” patients will benefit from the facility. The letters provided by the applicant do not support the statement that there will be up to 300 referrals from these physicians to the proposed facility each year.

Even if it is assumed that all 300 patients referenced in the three physician letters are referred to the proposed facility, the applicant projects to serve 468 patients in its first full fiscal year following project completion. The applicant provides no support for its assumption that it will serve 168 additional patients in the first full fiscal year following project completion (and more patients in subsequent years).

- The applicant provides a map in Section C, page 39, which shows the area within a 30-mile radius of the proposed facility. Only small portions of Mecklenburg and Cabarrus

counties are included within the 30-mile radius, but the applicant includes the entire patient population for each county. The applicant provides no information to support the reasonableness of its projections applying to the entire patient population of those two counties, particularly considering Mecklenburg County is where the sole existing dedicated vascular access ASF in any of HSAs I, II, or III is located.

### **Access to Medically Underserved Groups**

In Section C, page 60, the applicant states:

*“Vascular ASC will be equally accessible to all persons, including those with low income, racial and ethnic minority groups, women, people with disabilities, the elderly, and Medicare beneficiaries, and Medicaid recipients.*

*Most of the patients proposed to be served by Vascular ASC can be classified into one or more categories of medically underserved groups, .... The specific needs of any other patient ... will be assessed in that patient’s care plan. Vascular ASC will be available to all in need of vascular access services without discrimination.”*

In Section C, page 60, the applicant provides the estimated percentage of patients it projects to serve in its third full fiscal year of operation, for each medically underserved group, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low income persons	5.0%
Racial and ethnic minorities	50.0%
Women	40.0%
Persons with disabilities	10.0%
Persons 65 and older	85.0%
Medicare beneficiaries	85.0%
Medicaid recipients	5.0%

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 based on the following:

- The applicant provides a statement that it will provide access to the proposed services for medically underserved groups.
- The applicant provides a copy of the proposed Non-Discrimination Policy to be used at Vascular ASC in Exhibit C.6 and which is consistent with the applicant’s statements on page 60.

### **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 not conforming to this criterion for all the reasons described above.

- (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 [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

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.

NC

The applicant proposes to develop a new dedicated vascular access ASF, Vascular ASC, by developing one OR pursuant to the adjusted need determination for HSA III in the 2023 SMFP.

In Section E, page 71, 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:

- Maintain the Status Quo: the applicant states maintaining the status quo does not address need for additional vascular access OR capacity or for a vascular access ASF that will treat all patients regardless of ability to pay; therefore, this was not an effective alternative.
- Constructing a New ASF Instead of Upfitting Existing Space: the applicant states that since there will be only one OR, developing a new facility and acquiring land would not be financially feasible; therefore, this was not an effective alternative.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant does not demonstrate the need for the proposed project because projected utilization is not reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. A project which cannot demonstrate the need for the proposed project with reasonable and adequately supported utilization projections is not the most effective alternative to meet the need.
- The applicant does not demonstrate that the financial feasibility of the proposal is reasonable and adequately supported. The discussion regarding financial feasibility found in Criterion (5) is incorporated herein by reference. If the applicant cannot demonstrate that developing the project is financially feasible, the applicant cannot demonstrate the proposed alternative is the most effective alternative to meet the need.
- The applicant does not demonstrate that the proposed project is not an unnecessary duplication of existing or approved health service capabilities or facilities. The discussion about unnecessary duplication found in Criterion (6) is incorporated herein by reference. A project that is unnecessarily duplicative cannot be the most effective alternative to meet the need.
- The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

### **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 not conforming to this criterion for the reasons stated above. Therefore, the application is denied.

- (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.

NC

The applicant proposes to develop a new dedicated vascular access ASF, Vascular ASC, by developing one OR pursuant to the adjusted need determination for HSA III in the 2023 SMFP.

### **Capital and Working Capital Costs**

On Form F.1a in Section Q, the applicant provides the projected capital cost, as shown in the table below.

<b>Category</b>	<b>Proposed Capital Costs</b>
Construction/Renovation Contract(s)/Site Prep	\$2,300,000
Architect & Engineering Fees	\$267,000
Medical Equipment	\$521,835
Equipment & Furniture	\$75,000
Consultant Fees	\$15,000
Interest During Construction	\$175,505
Contingency	\$200,000
DHSR Review Fee	\$4,000
<b>Total</b>	<b>\$3,558,340</b>

In Exhibit F.1, the applicant provides the assumptions and methodology used to project capital costs.

The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Exhibit F.1 contains a letter dated August 4, 2023, from a licensed architect, which matches the projected construction, site preparation, and architect/engineering fees projected in Form F.1a.
- In Exhibit F.1, the applicant also provides an itemized list of medical equipment with estimated costs.

In Section F, page 75, the applicant projects start-up costs of \$217,095 and initial operating costs of \$275,000 over an initial operating period of three months for a total projected working capital cost of \$492,095.

In Section F, page 76, 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 based on the following:

- The applicant identifies the individual components of the projected start-up costs.
- The applicant explains the assumptions used in projecting the initial operating expenses and the expected timeframe for the initial operating period.

**Availability of Funds**

In Section F, pages 73 and 77, the applicant states that \$3,533,962 of the capital cost and the entire working capital cost of \$492,095 will be financed by loans.

In Exhibit F.3, the applicant provides a letter from Piedmont Federal Savings Bank and a separate letter from American National Bank & Trust Company. Both letters state that the bank is aware projected capital costs will be approximately \$3.6 million and working capital costs will be approximately \$500,000, and state they are willing to consider providing a loan to the applicant. The applicant also includes amortization tables for the proposed loans in Exhibit F.3. Finally, the applicant provides a letter stating that it will commit the funding from loans to developing the facility.

On page 73, in responding to the question regarding funding sources for capital costs, the applicant appears to leave off approximately \$24,378 of the projected capital cost. However, both letters from banks in Exhibit F.3 provide for loan amounts that would be sufficient to fund the actual projected capital cost; therefore, the applicant provides sufficient support to document the availability of funds for the proposed project.

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

- The applicant provides a letter stating it will commit funds from the loans to developing the proposed project.
- The applicant provides two separate letters from different banks offering to provide the loans necessary to fund the proposed project and includes the related amortization tables.

**Financial Feasibility**

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

<b>Revenues and Operating Expenses – Vascular ASC</b>			
	<b>1<sup>st</sup> Full FY FFY 2026</b>	<b>2<sup>nd</sup> Full FY FFY 2027</b>	<b>3<sup>rd</sup> Full FY FFY 2028</b>
Total Surgical Cases	983	1,311	1,311
Total Gross Revenues (Charges)	\$7,252,277	\$9,959,794	\$10,258,588
Total Net Revenue	\$2,404,130	\$3,205,659	\$3,205,809
Total Net Revenue per Surgical Case	\$2,446	\$2,445	\$2,445
Total Operating Expenses (Costs)	\$2,126,741	\$2,328,543	\$2,360,465
Total Operating Expenses per Surgical Case	\$2,164	\$1,776	\$1,801
<b>Net Income/(Loss)</b>	<b>\$277,389</b>	<b>\$877,116</b>	<b>\$845,344</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Forms F.2b and F.3b in Section Q. However, the applicant does not adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported because projected utilization is not based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference. Therefore, projected revenues and operating expenses, which are based in part on projected utilization, are also questionable.

### **Conclusion**

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 not conforming to this criterion because the applicant does not adequately demonstrate 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.

NC

The applicant proposes to develop a new dedicated vascular access ASF, Vascular ASC, by developing one OR pursuant to the adjusted need determination for HSA III in the 2023 SMFP.

On page 47, the 2023 SMFP defines the service area for ORs as “...*the single or multicounty grouping shown in Figure 6.1.*” Figure 6.1 on page 53 of the 2023 SMFP shows Iredell County as its own OR service area. Ordinarily, the service area for this project would be Iredell County; however, pursuant to the adjusted need determination on page 79 of the 2023 SMFP, the service area for this project is HSA III. Facilities may also serve residents of counties not included in their service area.

Tables 6A and 6B in Chapter 6 of the 2023 SMFP show HSA III has 20 existing and approved hospitals and 21 existing and approved ASFs offering ambulatory surgical services. Information about each of the facilities is shown in the table below.

<b>HSA III ORs – Hospitals &amp; ASFs</b>				
<b>Facility</b>	<b>Hospital/ASF</b>	<b>Location</b>	<b>ORs*</b>	<b>(Surplus)/Deficit</b>
Gateway Surgery Center	ASF	Cabarrus	6	(2.50)
Atrium Health Cabarrus	Hospital	Cabarrus	17	0.66
Eye Surgery and Laser Clinic	ASF	Cabarrus	2	0.20
CaroMont ASC – Belmont	ASF	Gaston	2	**
CaroMont Specialty Surgery	ASF	Gaston	3	(1.74)
CaroMont Regional Medical Center - Belmont	Hospital	Gaston	2	**
CaroMont Regional Medical Center	Hospital	Gaston	17	(5.03)
Statesville Orthopedic Surgery Center	ASF	Iredell	1	**
Iredell Ambulatory Surgery Center	ASF	Iredell	1	(0.76)
Iredell Surgical Center	ASF	Iredell	4	(3.50)
Iredell Surgery at Mooresville	ASF	Iredell	1	**
Davis Regional Medical Center	Hospital	Iredell	4	(2.07)
Lake Norman Regional Medical Center	Hospital	Iredell	9	(5.27)
Iredell Memorial Hospital	Hospital	Iredell	9	(1.65)
Atrium Health Lincoln	Hospital	Lincoln	4	(1.36)
Atrium Health Huntersville Surgery Center	ASF	Mecklenburg	1	**
Carolina Center for Specialty Surgery	ASF	Mecklenburg	3	(0.95)
SouthPark Surgery Center	ASF	Mecklenburg	6	0.14
Novant Health Ballantyne Outpatient Surgery	ASF	Mecklenburg	2	(0.30)
Novant Health Huntersville Outpatient Surgery	ASF	Mecklenburg	2	(0.49)
Mathews Surgery Center	ASF	Mecklenburg	2	0.00
Charlotte Surgery Center – Museum	ASF	Mecklenburg	6	(1.62)
Charlotte Surgery Center – Wendover	ASF	Mecklenburg	6	(0.15)
Mallard Creek Surgery Center	ASF	Mecklenburg	2	0.04
Metrolina Vascular Access Care	ASF	Mecklenburg	1	**
Valleygate Dental Surgery Center Charlotte	ASF	Mecklenburg	2	***
Atrium Health Lake Norman	Hospital	Mecklenburg	2	**
Atrium Health Pineville	Hospital	Mecklenburg	13	(0.54)
Atrium Health University City	Hospital	Mecklenburg	6	(1.03)
Carolinas Medical Center	Hospital	Mecklenburg	68	(3.30)
Novant Health Ballantyne Medical Center	Hospital	Mecklenburg	2	**
Novant Health Steele Creek Medical Center	Hospital	Mecklenburg	2	**
Novant Health Presbyterian Medical Center	Hospital	Mecklenburg	35	0.79
Novant Health Mathews Medical Center	Hospital	Mecklenburg	7	0.63
Novant Health Huntersville Medical Center	Hospital	Mecklenburg	7	(0.67)
Novant Health Mint Hill Medical Center	Hospital	Mecklenburg	3	(1.38)
Novant Health Rowan Medical Center	Hospital	Rowan	11	(2.02)
Atrium Health Stanly	Hospital	Stanly	5	(3.43)
Presbyterian SameDay Surgery Center-Monroe	ASF	Union	1	**
Atrium Health Surgery Center Indian Trail	ASF	Union	3	(2.61)
Atrium Health Union	Hospital	Union	6	(0.35)
<b>Total</b>			<b>286</b>	<b>(54.26)</b>

\* Number of ORs in Adjusted Planning Inventory

\*\* Facility that is not operational or has not yet provided data for the SMFP. These facilities have a surplus equal to the number of ORs in their adjusted planning inventory.

\*\*\* Demonstration project with ORs excluded from need methodology in the 2023 SMFP

In Section G, page 83, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved ORs in HSA III. The applicant states:

*“Vascular ASC proposes to develop one operating room in a single-specialty ASF, which will not result in an unnecessary duplication of existing or approved facilities because 1) the proposed project does not exceed the vascular access OR need determination in HSA III in the 2023 SMFP, 2) the existing vascular access OR in HSA III operates in Charlotte (43 miles from the proposed ASF), and 3) Vascular ASC offers a new independent, physician-owned, alternative provider to increase patient access to vascular access services.”*

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant does not demonstrate that projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. A project which cannot demonstrate the need for the proposed project by not providing reasonable and adequately supported utilization projections, cannot demonstrate that the project is not an unnecessary duplication of existing or approved services in the service area.

### **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 not conforming to this criterion for all the reasons described 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

The applicant proposes to develop a new dedicated vascular access ASF, Vascular ASC, by developing one OR pursuant to the adjusted need determination for HSA III in the 2023 SMFP.

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services during the first three full fiscal years following project completion, as shown in the table below.

<b>Proposed Staffing in FTEs – Vascular ASC – FYs 1-3 (FFYs 2026-2028)</b>	
<b>Position</b>	<b>FTEs</b>
Administrator	1.0
Registered Nurses	2.2
Nurse Assistant	1.0
Surgical Technician	1.0
PRN Surgical Technician	0.1
Radiology Technician	1.0
PRN Radiology Technician	0.1
Financial Specialist	1.0
Receptionist/Patient Intake Specialist	1.0
<b>Total FTEs</b>	<b>8.4</b>

The assumptions and methodology used to project staffing are provided immediately following Form H in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted on Form F.3b in Section Q. In Section H, pages 88-89, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs and provides supporting documentation in Exhibits H.2 and H.3.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant states that projected staffing is “*based on expected volume with appropriate staffing requirements*” and projected salaries are based on area averages.
- Exhibit H.2 contains the applicant’s proposed equal employment opportunity policy.
- In Exhibit H.3, the applicant provides numerous job position listings and their descriptions.

### **Conclusion**

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 for all the reasons described 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

The applicant proposes to develop a new dedicated vascular access ASF, Vascular ASC, by developing one OR pursuant to the adjusted need determination for HSA III in the 2023 SMFP.

### **Ancillary and Support Services**

In Section I, page 91, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, page 92, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant explains why each service is necessary and which services are not necessary.
- In Exhibit I.1, the applicant provides a letter stating it will provide the necessary ancillary and support services.

### **Coordination**

In Section I, page 93, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits C.4 and I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant states it has established relationships with area providers that have existed for many years.
- In Exhibit C.4, the applicant provides letters of support from local physicians.
- In Exhibit I.2, the applicant provides a proposed transfer agreement.

### **Conclusion**

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 for all the reasons described 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

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

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

The applicant proposes to develop a new dedicated vascular access ASF, Vascular ASC, by developing one OR pursuant to the adjusted need determination for HSA III in the 2023 SMFP.

In Section K, page 96, the applicant states that the project involves constructing 3,600 square feet of new space and renovating 891 square feet of existing space. Line drawings are provided in Exhibit K.1.

In Section K, pages 98-99, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal, and power at the site. Supporting documentation is provided in Exhibits F.2 and K.4. The site appears to be suitable for the proposed ASF based on the applicant's representations and supporting documentation.

In Section K, page 96, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative based on the following:

- The applicant refers to its discussion on alternatives found in Criterion (4), which is incorporated herein by reference.
- The applicant states in Section E, page 71, that upfitting and constructing additional space is more financially feasible than constructing a new building.

In Section K, page 97, 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 based on the following:

- The applicant states that, based on the expertise of the project architect, the proposed construction is necessary to develop the proposed facility.
- In Exhibit F.3, the applicant provides the proposed lease term sheet for the proposed facility renovation and upfit.

In Section K, page 97, 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

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

NA

Vascular 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;

NA

Vascular 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

In Section L, page 104, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

<b>Vascular ASC Projected Payor Mix FFY 2028</b>	
<b>Payment Source</b>	<b>% of Total Patients</b>
Medicare*	85.0%
Medicaid*	5.0%
Insurance*	5.0%
Other (Other government)	5.0%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 85% of services will be provided to Medicare patients and 5% of services to Medicaid patients.

On page 104, 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 because the applicant relied on the experience of nephrologists who have referred their patients for vascular access services.

### **Conclusion**

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 for all the reasons described 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

In Section L, page 105, the applicant adequately describes the range of means by which patients will have access to the proposed services.

### **Conclusion**

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

The applicant proposes to develop a new dedicated vascular access ASF, Vascular ASC, by developing one OR pursuant to the adjusted need determination for HSA III in the 2023 SMFP.

In Section M, page 107, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant states that it will have a positive and close working relationship with health care training programs.
- In Exhibit M.1, the applicant provides copies of letters sent from the applicant to four local health professional training programs, offering Vascular ASC as a training site.
- Exhibit M.1 also contains a proposed training site agreement to be used with local health professional training programs.

**Conclusion**

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 for all the reasons described above.

- (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.

NC

The applicant proposes to develop a new dedicated vascular access ASF, Vascular ASC, by developing one OR pursuant to the adjusted need determination for HSA III in the 2023 SMFP.

On page 47, the 2023 SMFP defines the service area for ORs as “...*the single or multicounty grouping shown in Figure 6.1.*” Figure 6.1 on page 53 of the 2023 SMFP shows Iredell County as its own OR service area. Ordinarily, the service area for this project would be Iredell County; however, pursuant to the adjusted need determination on page 79 of the 2023 SMFP, the service area for this project is HSA III. Facilities may also serve residents of counties not included in their service area.

Tables 6A and 6B in Chapter 6 of the 2023 SMFP show HSA III has 20 existing and approved hospitals and 21 existing and approved ASFs offering ambulatory surgical services. Information about each of the facilities is shown in the table below.

<b>HSA III ORs – Hospitals &amp; ASFs</b>				
<b>Facility</b>	<b>Hospital/ASF</b>	<b>Location</b>	<b>ORs*</b>	<b>(Surplus)/Deficit</b>
Gateway Surgery Center	ASF	Cabarrus	6	(2.50)
Atrium Health Cabarrus	Hospital	Cabarrus	17	0.66
Eye Surgery and Laser Clinic	ASF	Cabarrus	2	0.20
CaroMont ASC – Belmont	ASF	Gaston	2	**
CaroMont Specialty Surgery	ASF	Gaston	3	(1.74)
CaroMont Regional Medical Center - Belmont	Hospital	Gaston	2	**
CaroMont Regional Medical Center	Hospital	Gaston	17	(5.03)
Statesville Orthopedic Surgery Center	ASF	Iredell	1	**
Iredell Ambulatory Surgery Center	ASF	Iredell	1	(0.76)
Iredell Surgical Center	ASF	Iredell	4	(3.50)
Iredell Surgery at Mooresville	ASF	Iredell	1	**
Davis Regional Medical Center	Hospital	Iredell	4	(2.07)
Lake Norman Regional Medical Center	Hospital	Iredell	9	(5.27)
Iredell Memorial Hospital	Hospital	Iredell	9	(1.65)
Atrium Health Lincoln	Hospital	Lincoln	4	(1.36)
Atrium Health Huntersville Surgery Center	ASF	Mecklenburg	1	**
Carolina Center for Specialty Surgery	ASF	Mecklenburg	3	(0.95)
SouthPark Surgery Center	ASF	Mecklenburg	6	0.14
Novant Health Ballantyne Outpatient Surgery	ASF	Mecklenburg	2	(0.30)
Novant Health Huntersville Outpatient Surgery	ASF	Mecklenburg	2	(0.49)
Matthews Surgery Center	ASF	Mecklenburg	2	0.00
Charlotte Surgery Center – Museum	ASF	Mecklenburg	6	(1.62)
Charlotte Surgery Center – Wendover	ASF	Mecklenburg	6	(0.15)
Mallard Creek Surgery Center	ASF	Mecklenburg	2	0.04
Metrolina Vascular Access Care	ASF	Mecklenburg	1	**
Valleygate Dental Surgery Center Charlotte	ASF	Mecklenburg	2	***
Atrium Health Lake Norman	Hospital	Mecklenburg	2	**
Atrium Health Pineville	Hospital	Mecklenburg	13	(0.54)
Atrium Health University City	Hospital	Mecklenburg	6	(1.03)
Carolinas Medical Center	Hospital	Mecklenburg	68	(3.30)
Novant Health Ballantyne Medical Center	Hospital	Mecklenburg	2	**
Novant Health Steele Creek Medical Center	Hospital	Mecklenburg	2	**
Novant Health Presbyterian Medical Center	Hospital	Mecklenburg	35	0.79
Novant Health Matthews Medical Center	Hospital	Mecklenburg	7	0.63
Novant Health Huntersville Medical Center	Hospital	Mecklenburg	7	(0.67)
Novant Health Mint Hill Medical Center	Hospital	Mecklenburg	3	(1.38)
Novant Health Rowan Medical Center	Hospital	Rowan	11	(2.02)
Atrium Health Stanly	Hospital	Stanly	5	(3.43)
Presbyterian SameDay Surgery Center-Monroe	ASF	Union	1	**
Atrium Health Surgery Center Indian Trail	ASF	Union	3	(2.61)
Atrium Health Union	Hospital	Union	6	(0.35)
<b>Total</b>			<b>286</b>	<b>(54.26)</b>

\* Number of ORs in Adjusted Planning Inventory

\*\* Facility that is not operational or has not yet provided data for the SMFP. These facilities have a surplus equal to the number of ORs in their adjusted planning inventory.

\*\*\* Demonstration project with ORs excluded from need methodology in the 2023 SMFP



Regarding the expected effects of the proposal on competition in the service area, in Section N, page 110, the applicant states:

*“..., the development of Vascular ASC in HSA III will offer high-quality, cost-effective, and easily accessible care. The presence of Vascular ASC will improve the competitive landscape, drive innovation, and ultimately enhance the overall quality of care patients receive.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 110, the applicant states:

*“Vascular ASC will provide a more economical choice for vascular access services to the patients in HSA III. As a new ASF, Vascular ASC will focus on developing an efficiently operated ASF through the facility’s design, policies and procedures, staffing, and space utilization. An ASF typically provides a less expensive option to the insurer and, therefore, to the patient for similar ambulatory procedures performed in other settings.”*

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

Regarding the impact of the proposal on quality, in Section N, page 111, the applicant states:

*“Vascular ASC will establish a performance improvement program. The objective of a performance improvement program will be to provide an ongoing evaluation of various aspects of Vascular ASC’s operations, both medical and non-medical. Moreover, at such time as this evaluation process reveals questions associated with a facet of Vascular ASC’s operations, the program will provide a methodology to monitor, analyze, and improve performance.”*

See also Sections B, 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 112, the applicant states:

*“Vascular ASC will not discriminate against any class of patient based on age, sex, religion, race, [disability], ethnicity, or ability to pay. Vascular ASC will actively participate in both the Medicaid and Medicare programs.”*

See also Sections B, C, D, and L of the application and any exhibits.

However, the applicant does not adequately demonstrate the proposal would have a positive impact on cost-effectiveness because the applicant does not adequately demonstrate:

- the need the population to be served has for the proposal. The discussion regarding need, including projected utilization, found in Criterion (3) is incorporated herein by reference;

- that the proposal would not result in an unnecessary duplication of existing and approved health services. The discussion regarding unnecessary duplication found in Criterion (6) is incorporated herein by reference; and
- that projected revenues and operating costs are reasonable. The discussion regarding projected revenues and operating costs found in Criterion (5) 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 not 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.

NA

Neither the applicant nor any related entities own, operate, or manage an existing health service facility located in North Carolina. Therefore, Criterion (20) is not applicable to this review.

(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.

NC

The Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100 are applicable to this review.

**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 in effect at the time the review began. The applicant is not required to use the population growth factor.*
- NC- On Form C.3b, the applicant projects a need for 1.1 ORs in the third full fiscal year following project completion. However, the applicant does not adequately demonstrate projections are based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming with this Rule.
- (b) *The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.*
- NC- In the Utilization Methodology and Assumptions subsection of Section Q, the applicant provided the assumptions and methodology used for projected utilization. However, the applicant does not adequately demonstrate projections are based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming with this Rule.