

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 17, 2024

Findings Date: January 17, 2024

Project Analyst: Cynthia Bradford

Co-Signer: Mike McKillip

Project ID #: L-12435-23

Facility: Carolina Vascular Care

FID #: 230894

County: Nash

Applicant(s): Carolina Vascular Care, PLLC

Project: Develop a new ASF with no more than one dedicated vascular access operating room and one procedure room 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.

C

Carolina Vascular Care, PLLC (hereinafter referred to as “the applicant”) proposes to develop a new ambulatory surgical facility (ASF) with no more than one dedicated vascular access operating room and one procedure room pursuant to the need determination in the 2023 SMFP.

Need Determination

The 2023 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional operating rooms in North Carolina by service area. In response to a petition, the State Health Coordinating Council approved an adjusted need determination for one dedicated vascular access OR in each of the six HSAs in the State. This application is to develop a new vascular access OR in HSA VI.

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

Policy GEN-3: Basic Principles 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.”

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B (a) and (d), pages 27 and 29, Section N.2, pages 118-119, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B(b) and (d), pages 27-28; Section C.6, pages 64-65; Section L, page 114; Section N.2, page 119, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B (c) and (d), page 27-28; Section K, page 103, Section N, page 117; the applicant’s pro forma financial statements in Section Q and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

The information provided by the applicant is reasonable and adequately demonstrates how its proposal incorporates the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2023 SMFP. Therefore, the application is consistent with Policy GEN-3.

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.”

The proposed capital expenditure for this project is more than \$4 million, but less than \$5 million. In Section B, page 30, 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

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

- The applicant does not propose to develop more operating rooms than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 based on the following reasons:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of operating room services in Nash County.
 - The applicant adequately documents how the project will promote equitable access to operating room services in Nash County.

- The applicant adequately documents how the project will maximize healthcare value for the resources expended.
 - The applicant’s projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2023 SMFP.
 - 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.

C

The applicant proposes to develop a new ASF with no more than one dedicated vascular access operating room and one procedure room pursuant to the need determination in the 2023 SMFP.

In Section C.1, page 31, the applicant states that,

“Carolina Vascular Care, PLLC (or “Applicant”), proposes to develop one new dedicated vascular access operating room in a new licensed and accredited and CMS certified single specialty ambulatory surgical center (“ASC”) in Rocky Mount, Nash County. The proposed project is in response to the 2023 SMFP need determination for one dedicated vascular access operating room in HSA VI. Carolina Vascular Care, PLLC operates an office-based lab with one procedure room in Rocky Mount, Nash County. The OBL opened November 1, 2022. Upon opening the proposed new ASF, Carolina Vascular Care, PLLC will transfer existing patients, staff, and services to the new single-specialty ASF, that will be called Carolina Vascular Care (“CVC”).”

Patient Origin

On page 47, the 2023 SMFP defines the services area for ORs as *“the single or multicounty grouping shown in Figure 6.1.”* In Figure 6.1, page 53 of the 2023 SMFP, Nash County is shown as a single county operating room service area. However, pursuant to the adjusted need determination on page 74 of the 2023 SMFP, the service area for this project is HSA VI. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 40, the applicant states that Carolina Vascular Care, PLLC (CVC) does not currently operate an ASC. The following table summarizes historical patient origin for existing office-based lab (OBL) for the time period from November 1, 2022 through September 30, 2023.

Carolina Vascular Care (OBL) Historical Patient Origin 11/01/2022 to 09/30/2023		
County	Patients	% of Total
Edgecombe	32	5.3%
Nash	110	18.2%
Halifax	293	48.5%
Wilson	42	7.0%
Wayne	89	14.7%
Remainder of HSA VI	20	3.3%
Other Counties and States	18	3.0%
Total	604	100.0%

In Section C, page 42, the applicant provides the projected patient origin for the first three full fiscal years at Carolina Vascular Care, as summarized below.

Carolina Vascular Care Operating Room Projected Patient Origin FY2025-FY2027						
County	1st Full FY 1/1/2025-12/31/2025		2nd Full FY 1/1/2026-12/31/2026		3rd Full FY 1/1/2027-12/31/2027	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Nash	39	5.3%	42	5.3%	44	5.3%
Edgecombe	135	18.2%	143	18.2%	152	18.2%
Halifax	360	48.5%	382	48.5%	405	48.5%
Wilson	52	7.0%	55	7.0%	58	7.0%
Wayne	109	14.7%	116	14.7%	123	14.7%
Remainder of HSA VI	25	3.3%	26	3.3%	28	3.3%
Other Counties and States	22	3.0%	23	3.0%	25	3.0%
Total	743	100.0%	788	100.0%	835	100.0%

In Section Q, the applicant provides the assumptions and methodology (Step 9) used to project patient origin for Carolina Vascular Care. The applicant states that projected patient origin for the operating room and procedure rooms at CVC is based on the FY2022/2023 patient origin of procedures performed in its OBL.

The applicant's patient origin projections are reasonable and adequately supported because they are based on CVC's historical experience in its OBL.

Analysis of Need

In Section C, pages 44-58, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 44, the applicant states the specific need for the project is based on the following factors:

- Need identified in the 2023 SMFP for one dedicated vascular access operating room in HSA VI (page 45)
- Changes in reimbursement (pages 45-48)
- Historical utilization of vascular access services in the area (pages 49-52)
- Area health status and demographics (pages 52-57)

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

- The applicant provides information regarding the reimbursement cuts that have created multiple OBL closures over the past few years.
- The applicant cites their current utilization of vascular procedures in their existing OBL.
- The applicant provides historical and projected population growth statistics for the Nash County and historical service area population to be served and the continued demand for the services proposed.

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Projected Utilization

In Section Q, Form C.3b, the applicant provides the projected utilization for Carolina Vascular Care for the first three full fiscal years upon project completion, as illustrated in the following table.

Carolina Vascular Care Projected OR Utilization			
	1st Full FY CY2025	2nd Full FY CY2026	3rd Full FY CY2027
Operating Rooms			
Dedicated Ambulatory ORs	1	1	1
Total # of ORs	1	1	1
Surgical Cases			
# of Outpatient Surgical Cases	1,843	1,954	2,070
Total # of Surgical Cases	1,843	1,954	2,070
Case Times (in hours)			
Outpatient	1.1	1.1	1.1
Surgical Hours			
Outpatient	2,027	2,149	2,277
Total Surgical Hours	2,027	2,149	2,277
# of ORs Needed			
Group Assignment	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312
Total Surgical/Standard Hours per OR per Year	1.54	1.64	1.74

In Section Q Form C.3b, pages 129-144, the applicant provides the assumptions and methodology used to project operating room utilization, as summarized below:

Step 1: The applicant determined that 93.7 percent of CVC patients originated from five counties based on their first eleven months functioning as an OBL.

Step 2: The applicant first determined the total number of ESRD patients within the five-county area by using data from the proposed 2024 SMFP, and then calculated a compound annual growth rate (“CAGR”) of estimated ESRD patients from 2018 to 2022, as shown in the table below.

ESRD Patients by County, CVC Catchment Area, 2018-2022						
County	CY2018	CY2019	CY2020	CY2021	CY2022	CAGR
Edgecombe	224	247	247	264	305	8.0%
Halifax	242	237	253	259	237	-0.5%
Nash	288	273	293	303	290	0.2%
Wayne	309	326	315	313	321	1.0%
Wilson	298	285	316	314	284	-1.2%
Total	1,361	1,368	1,424	1,453	1,437	1.4%

Source: Section Q, page 133, Assumptions and Methodology

Step 3: The applicant estimated the number of ESRD patients in the catchment area, CY2023-CY2027 by applying the four-year CAGR at 85 percent, as shown in the table below.

Estimated ESRD Patients by County, CVC Catchment Area, 2023-2027						
County	Adjusted CAGR	CY2023	CY2024	CY2025	CY2026	CY2027
Edgecombe	6.8%	326	348	372	397	424
Halifax	-0.4%	236	235	234	233	232
Nash	0.1%	290	291	291	292	292
Wayne	0.8%	324	326	329	332	334
Wilson	-0.1%	281	278	275	273	270
Total	1.2%	1,457	1,478	1,501	1,526	1,552

Source: Section Q, page 134, Assumptions and Methodology

Adjusted CAGR = CAGR by County * 0.85

Total patients = previous year patients * (1 + adjusted CAGR)

Step 4: The applicant then applied the 2.0 procedures per patient average to the estimated number of ESRD patients in the five-county area. This results in an estimated 3,702 procedures needed by 2027 as shown in the table below.

Estimated Vascular Access Procedures by County, CVC Catchment Area, 2023-2027						
County	CY2023	CY2024	CY2025	CY2026	CY2027	
Edgecombe	652	696	743	794	848	
Halifax	472	470	468	466	464	
Nash	581	582	583	583	584	
Wayne	647	652	658	663	669	
Wilson	562	557	551	545	540	
Total	2,914	2,957	3,002	3,052	3,104	

Source: Section Q, page 135, Assumptions and Methodology

Step 5: The applicant annualized this data to determine its estimated patient totals by county for CY2023. The applicant states that approximately 93.7 percent of CVC patients originate from the five-county area. The remaining 6.5 percent includes residents of the other 24 counties of HSA VI, other NC counties, and other states as shown in the table below.

CVC Historical Vascular Access Patients by County November 2022 through September 2023			
County	Total to Date	11 Months Annualized	Percent Total
Edgecombe	32	35	5.3%
Halifax	110	120	18.2%
Nash	293	320	48.5%
Wayne	42	46	7.0%
Wilson	89	97	14.7%
Five-County Area	566	617	93.7%
Remaining HSA VI	20	22	3.3%
Other	18	20	3.0%
Total Patients	604	659	100.0%

Source: Section Q, page 136, Assumptions and Methodology

Step 6: The Applicant divided its CY2023 annualized vascular access patients from the five-county area by the total estimated 2023 ESRD patients from the same counties.

CVC Historical Vascular Access Patients as a Percent of ESRD Patients, Five-County Area, 2023	
CVC Annualized CY23 Patients	617
Estimated ESRD CY23 Patients	1,457
CVC Market Share	42.4%

Source: Section Q, page 137, Assumptions and Methodology

Step 7: The applicant estimates its market share will grow at 2.0 percent annually through the third year of operation. This equates to about 40 additional patients per year, less than four per month.

Estimated Total CVC Vascular Access Procedures, 5-County Area, 2023-2027					
Metric	CY2023	CY2024	CY2025	CY2026	CY2027
Total Catchment Area ESRD Patients	1,457	1,478	1,501	1,526	1,552
CVC Market Share	42.4%	44.4%	46.4%	48.4%	50.4%
Total CVC Patients	617	656	696	738	782

Source: Section Q, page 137, Assumptions and Methodology

Step 8: The applicant states CVC has treated 6.3 percent of patients from counties outside the catchment area, and the percentage has been relatively stable.

Estimated Total CVC Vascular Access Patients after In-migration, 2024-2027					
Metric	CY2023	CY2024	CY2025	CY2026	CY2027
Total Catchment Area Patients	617	656	696	738	782
In-Migration Percentage	6.3%	6.3%	6.3%	6.3%	6.3%
Total CVC Procedures	659	700	743	788	835

Source: Section Q, page 139, Assumptions and Methodology

Step 9: The applicant assumes its historical patient distribution from Step 5 will remain constant through CY2027. CVC therefore multiplied the estimated total patients from Step 8 by the percent distribution by county from Step 5, as shown in the table below.

Estimated Total CVC Vascular Access Patients, 2023-2027						
Geographic Area	Annualized % Distribution	CY2023	CY2024	CY2025	CY2026	CY2027
Edgecombe	5.3%	35	37	39	42	44
Halifax	18.2%	120	128	135	143	152
Nash	48.5%	320	340	360	382	405
Wayne	7.0%	46	49	52	55	58
Wilson	14.7%	97	103	109	116	123
Remaining HSA VI	3.3%	22	23	25	26	28
Other	3.0%	20	21	22	23	25
Total CVC Patients	100.0%	659	700	743	788	835

Source: Section Q, page 140, Assumptions and Methodology

Step 10: The applicant projected the number of vascular access procedures at CVC and determined its own historical average number of procedures per patient. Based on this result, CVC assumes its patients will need 2.5 vascular access procedures annually.

CVC Average Procedures per Patient, November 2022 – September 2023	
Total Unique Patients	604
Total Procedures	1,501
Procedures/Patient	2.5

Source: Section Q, page 141, Assumptions and Methodology

The applicant then applied the 2.5 procedures per patient average to the estimated number of total CVC patients by county from Step 9. This results in an estimated 1,914 procedures at CVC by 2027, as shown in the table below.

Estimated CVC Vascular Access Procedures, 2023-2027					
Geographic Area	CY2023	CY2024	CY2025	CY2026	CY2027
Edgecombe	87	92	98	104	110
Halifax	298	316	336	356	377
Nash	793	842	894	948	1,004
Wayne	114	121	128	136	144
Wilson	241	256	272	288	305
Remaining HSA VI	54	57	61	65	69
Other	49	52	55	58	62
Total CVC Procedures	1,634	1,736	1,843	1,954	2,070

Source: Section Q, page 141, Assumptions and Methodology

Step 11: The applicant calculated the adjusted estimated vascular access surgical hours in the 5-county area, 2023-2027. The applicant states the average procedure time for dialysis vascular access procedures is 60 minutes based on patient in / patient out calculations that include time to reset the room. It is therefore unnecessary to adjust annual surgical hours for dialysis vascular access procedures in the Five-county area because one procedure is equal to one hour.

- Table 12: The applicant divided the total number of procedures/surgical hours from Step 10 by 1,312 and demonstrates that by its third year of operation CVC will need 1.6 operating rooms.

Total CVC Vascular Access Patients after In-migration, 2024-2027					
Metric	CY2023	CY2024	CY2025	CY2026	CY2027
Total CVC Procedures	1,634	1,736	1,843	1,954	2,070
Standard Annual OR Surgical Hours	1,312	1,312	1,312	1,312	1,312
Total CVC ORs Needed	1.2	1.3	1.4	1.5	1.6

Source: Section Q, page 144, Assumptions and Methodology

- Table 13: The applicant states that the ASF will operate one shift for staffing and patient efficiency. To accommodate these surgical hours, the ASF will need one procedure room that is designed to the same specifications as the operating room. The logic of the standard operating room methodology for Nash County rounds to the nearest whole number any number equal to or exceeding 0.5.

	CY2023	CY2024	CY2025	CY2026	CY2027
Total Operating Rooms Proposed	1.0	1.0	1.0	1.0	1.0
Total Calculated Procedure Rooms Needed	0.2	0.3	0.4	0.5	0.6
Total Procedure Rooms Needed	0.0	0.0	0.0	1.0	1.0

Source: Section Q, page 144, Assumptions and Methodology

Projected utilization is reasonable and adequately supported based on the following:

- Projected utilization is based upon the historical OP surgery utilization at Carolina Vascular Care using internal data.
- The applicant projects utilization at Carolina Vascular Care will increase by the weighted CAGR for ESRD patients in a five-county area.
- Population projections and demographics support continued growth.
- Projected procedures in the proposed OR are based on historical data.

Access to Medically Underserved Groups

In Section C.6, page 64 the applicant states:

“All individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons aged 65 and older, and Medicare and Medicaid beneficiaries, as well as other underserved groups not listed here, will continue to have access to CVC’s vascular access service at the proposed ASC as clinically appropriate.”

On page 66, 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	% OF TOTAL PATIENTS
Low-income persons	58.0%
Racial and ethnic minorities	55.0%
Women	48.8%
Persons with disabilities	15.2%
The elderly	55.1%
Medicare beneficiaries	87.4%
Medicaid recipients	7.4%

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 applicant’s history of providing services to these patients at its existing OBL.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is 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 applicants do 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

The applicant proposes to develop a new ASF with no more than one dedicated vascular access operating room and one procedure room pursuant to the need determination in the 2023 SMFP.

In Section E.2, pages 74-80, the applicant describes the alternatives 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 planned reductions in payments for procedures threaten the financial viability of OBLs and as a result, Carolina Vascular Care, PLLC cannot continue to offer OBL services in the long term, because the Medicare payment schedule will drop below the cost of even the most efficient OBL. Therefore, this was not the most effective alternative. (pages 74-75)
- ***Offer vascular access procedures in existing hospital or ASC based operating rooms***- The applicant states hospitals do not offer routine maintenance dialysis care, a person who seeks care at a hospital for a dialysis access issue will most likely be scheduled for a next-day procedure. ESRD dialysis patients risk delays to accommodate more urgent hospital patients. This can be problematic for diabetic patients who are unable to fast for extended periods of time before a procedure this alternative more costly and less effective. (pages 75-77)
- ***Develop the proposal in another location within HSA VI*** – The applicant states that Carolina Vascular Care is an established OBL in the proposed service area and less than one mile from the proposed ASC. Patient and physician referral patterns can easily transfer to the proposed ASC. The facility location is easily accessible via Highways 64 and 301, and Interstate-95 making travel to CVC’s proposed ASC convenient for western communities of HSA VI. For these reasons, the applicant determined that developing the proposed ASC elsewhere in HSA VI is less effective. (pages 78-80)
- ***Convert the existing OBL to an ASC*** – The applicant considered converting its existing OBL to a licensed ASC. However, the space does not meet design guidelines for a single operating room certified ASC. Renovating the existing space to make it

compliant would require shutting down CVC for at least six months. This would limit access to vascular services and force patients to change their care patterns to facilities that are hours away in Greenville or Raleigh. Therefore, the applicant rejected this alternative as less effective. (page 79)

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why they believe the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above. Therefore, the application is approved subject to the following conditions:

- 1. Carolina Vascular Care, PLLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop a new ambulatory surgical facility with no more than one dedicated vascular access operating room.**
- 3. Upon project completion, Carolina Vascular Care 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 receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.**
 7. **For the first three years of operation following completion of the project, the certificate holder shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
 8. **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.**
- (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

The applicant proposes to develop a new ASF with no more than one dedicated vascular access operating room and one procedure room pursuant to the need determination in the 2023 SMFP.

Capital and Working Capital Costs

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

Construction Costs	\$3,130,050
Architect/Engineering	\$219,104
Medical Equipment	\$250,000
Consultant Fees	\$50,000
Interest During Construction	\$75,264
Tenet Improvement Allowance	(\$81,300)
Other- Contingency	\$364,312
Total	\$4,007,430

In Section Q, following Form F.1a, the applicants provide the assumptions used to project the capital cost.

In Section F.3, page 84, the applicant projects that start-up costs will be \$44,716 and initial operating expenses will be \$581,215 for a total working capital of \$625,932. In Section Q, page 147, 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 because the applicant identifies the costs included in the estimated start-up costs and initial operating expenses in Section F.4, pages 84-85, and Section Q, page 166 of the application.

Availability of Funds

In Section F.2, page 82, the applicant states that the capital cost will be funded by the applicant as shown in the table below.

Sources of Capital Cost Financing

TYPE	Carolina Vascular Care, PLLC	TOTAL
Loans	\$4,007,429	\$4,007,429
Accumulated reserves or OE*	\$0	\$0
Bonds	\$0	\$0
Other (funding from parent company)	\$0	\$0
Total Financing	\$4,007,429	\$4,007,429

In Section F, page 82, the applicant states that the capital costs of the project will be funded with a loan by the applicant. In Exhibit F.2, the applicant provides a letter dated October 6, 2023, from the Senior Vice President, for Simmons Bank documenting its intention to consider providing as much as \$4,800,000 to cover all capital costs of the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the 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 Section Q, Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

CAROLINA VASCULAR CARE	1 ST FULL FISCAL YEAR 1/1/2025- 12/31/2025	2 ND FULL FISCAL YEAR 1/1/2026- 12/31/2026	3 RD FULL FISCAL YEAR 1/1/2027- 12/31/2027
Total OR Cases^	1,843	1,954	2,070
Total Gross Revenues (Charges)	\$7,857,468	\$7,857,468	\$7,857,468
Total Net Revenue	\$3,221,562	\$3,221,562	\$3,221,562
Average Net Revenue per Case	\$1,750	\$1,648	\$1,556
Total Operating Expenses (Costs)	\$2,943,190	\$2,891,084	\$2,967,118
Average Operating Expense per Case	\$1,597	\$1,480	\$1,433
Net Income	\$278,372	\$330,478	\$254,444

^Source: Section Q, Form C.36, page 127.

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, page 153 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

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 and working capital are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- 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 costs and charges.

- (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

The applicant proposes to develop a new ASF with no more than one dedicated vascular access operating room and one procedure room pursuant to the need determination in the 2023 SMFP.

On page 47, the 2023 SMFP defines the services area for ORs as “the single or multicounty grouping shown in Figure 6.1.” In Figure 6.1, page 53 of the 2023 SMFP, Nash County is shown as a single county operating room service area. However, pursuant to the adjusted need

determination on page 74 of the 2023 SMFP, the service area for this project is HSA VI. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared operating rooms located in Nash County, and the inpatient and outpatient case volumes for each provider, from page of the 2023 SMFP.

Nash County Operating Room Inventory and Cases								
	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjust-ments	Adjusted Planning Inventory	IP Surgery Cases	OP Surgery Cases
Nash General Hospital	1	0	13	-1	0	13	1,336	6,651

Source: 2023 SMFP, Table 6A and Table 6B.

In Section G.2, page 92, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in the proposed service area. The applicant states:

“Although operating rooms in Nash County have excess capacity, UNC Nash Hospital does not offer routine ESRD vascular access maintenance procedures for other than emergency cases. It does not have an interventional nephrologist or vascular surgeon on its medical staff.”

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

- The applicant adequately demonstrates that the proposed operating room is needed in the service area.
- In response to a petition, the State Health Coordinating Council approved an adjusted need determination for one dedicated vascular access OR in each of the six HSAs in the State. This application is to develop a new vascular access OR in HSA VI.

Conclusion

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 for 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

The applicant proposes to develop a new ASF with no more than one dedicated vascular access operating room and one procedure room pursuant to the need determination in the 2023 SMFP.

In Section Q, Form H, the applicant provides projected full-time equivalent (FTE) positions for the proposed services, as summarized in the following table.

Carolina Vascular Care Projected FTE Positions			
Position	FY2025	FY2026	FY2027
Registered Nurses	4.24	4.78	5.31
CNAs/ Nursing Assistants	3.18	3.18	3.18
Interventional Nephrologist	1.59	1.59	2.12
Surgical Technicians	3.18	3.71	4.24
Business Office	1.06	1.06	1.06
Clerical	2.12	2.12	2.12
TOTAL	15.39	16.45	18.04

The assumptions and methodology used to project staffing are provided in Section Q, page 164. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3. In Section H.2, page 95, the applicant describes Carolina Vascular Care OBL's experience and process for recruiting and retaining staff 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 based on the following:

- The applicant has agreements with several community colleges and universities within Nash County.
- The applicant is active in the community at large and interacts consistently with area clinical training programs.
- The applicant works closely with educational programs to serve as a clinical training site, and benefits from having interactions with potential new hires.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

The applicant proposes to develop a new ASF with no more than one dedicated vascular access operating room and one procedure room pursuant to the need determination in the 2023 SMFP.

Ancillary and Support Services

In Section I.1, page 97, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 98-99, 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 following:

- The applicant identifies the necessary ancillary and support services for OR patients located in or near Nash County and how these will be made available.
- The applicant describes how the necessary ancillary and support services will be coordinated with the existing healthcare system.

Coordination

In Section I.2, page 99, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides documentation of these relationships in Exhibit 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 has established relationships with community health care and ancillary service providers where OR patients can receive appropriate referrals for necessary services related to their condition.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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.

- (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

In Section K, page 102, the applicant states that the project involves renovation of 8,130 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 103, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal. A cost certification letter is provided in Exhibit K.3. The applicant states,

“Guidelines for single specialty ASC’s will ensure careful budget control and efficient space use. The proposed construction approach will involve shopping for best prices. All construction plans will be subject to review by the NC Construction Section for both licensure and CMS Certification standards.”

On page 103, 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. The applicant states,

“This project will not increase the charges or projected reimbursement for the proposed services, which are established by Medicare, Medicaid, and/or existing private payor contracts. The applicant has concluded that the costs incurred to develop and operate this project are necessary and appropriate to ensure access for dialysis patients in the area.”

On page 104, 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

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

Carolina Vascular Care is not an existing health service facility. For information purposes, the following provides historical payor mix for the existing OBL that provides vascular access services. In Section L, page 107, the applicant provides the historical payor mix during the last 11 months (11/1/22 to 09/30/23) for vascular access services provided at their OBL, as shown in the following table:

Carolina Vascular Care HISTORICAL PAYOR MIX	
PAYOR CATEGORY	% OF TOTAL
Self Pay	1.0%
Medicare*	87.4%
Medicaid*	7.4%
Insurance*	2.2%
Other (VA, TriCare)	2.0%
Total	100.0%

*Including any managed care plans.

In Section L, page 109, the applicant provides the following comparison:

Carolina Vascular Care FY2022	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	48.8%	51.4%
Male	51.2%	48.6%
64 and Younger	44.9%	76.6%
65 and Older	55.1%	23.4%
American Indian	0.2%	2.7%
Asian	N/A	2.2%
Black or African-American*	8.7%	35.5%
White or Caucasian*	1.2%	55.2%
Other Race	N/A	4.3%
Declined / Unavailable	89.9%	

* The applicant states most patients declined to provide racial information.

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 documented 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.

- (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;

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 111, the applicant states the facility is not under any obligation to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 111, the applicant states that during the last 18 months immediately preceding the application deadline no patient civil rights access complaints have been filed against the facility or any related entities located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 112, 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:

Carolina Vascular Care PROJECTED PAYOR MIX 3RD FULL FY2027	
PAYOR CATEGORY	% OF TOTAL
Self Pay	1.0%
Medicare*	87.4%
Medicaid*	7.4%
Insurance*	2.2%
Other (Gov't)	2.0%
Total	100.0%

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 87.4% of total surgical services will be provided to Medicare patients and 7.4% to Medicaid patients.

In Section L, page 81 the applicant states that the projected payor mix is based on the FY2023 annualized payor mix for vascular access patients at its existing OBL.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 114, 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

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 ASF with no more than one dedicated vascular access operating room and one procedure room pursuant to the need determination in the 2023 SMFP.

In Section M, page 115, 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 letters of support from outside training facilities in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant has existing relationships and clinical training agreements with Nash Community College, Edgecombe Community College, Halifax Community College, Wilson Community College, and East Carolina University.
- The applicant provides clinical training site/letters of support in Exhibit M.1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is 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

The applicant proposes to develop a new ASF with no more than one dedicated vascular access operating room and one procedure room pursuant to the need determination in the 2023 SMFP.

On page 47, the 2023 SMFP defines the services area for ORs as “*the single or multicounty grouping shown in Figure 6.1.*” In Figure 6.1, page 53 of the 2023 SMFP, Nash County is shown as a single county operating room service area. However, pursuant to the adjusted need determination on page 74 of the 2023 SMFP, the service area for this project is HSA VI. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared operating rooms located in Nash County, and the inpatient and outpatient case volumes for each provider, from page of the 2023 SMFP.

Nash County Operating Room Inventory and Cases								
	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjust-ments	Adjusted Planning Inventory	IP Surgery Cases	OP Surgery Cases
Nash General Hospital	1	0	13	-1	0	13	1,336	6,651

Source: 2023 SMFP, Table 6A and Table 6B.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 116, the applicant states:

“CVC will promote competition in the service area because it will establish the first and only single specialty ambulatory surgical facility dedicated to vascular access.”

Regarding the impact of the proposal on cost-effectiveness, in Section N, page 117, the applicant states:

“Single-specialty ASFs, particularly CVC, which will be narrowly focused on vascular access procedures for renal dialysis patients, will have lower equipment and supply costs than multi-specialty ASF counterparts. Staff productivity will be higher because staff must master a narrower range of procedures.”

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

Regarding the impact of the proposal on quality, in Section N, pages 118-119, the applicant states:

“The facility will be licensed by North Carolina, certified by CMS and accredited by AAAHC. Thus, it will have many layers of third-party quality oversight.”

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 119, the applicant states:

“The facility will accept referred patients without regard to source of payment and CVC budgets provide for charity for medical necessity. CVC will accept most third-party commercial payors, including the State Employees Medical plan, Tricare for military veterans, Medicaid, and Medicare.”

See also Sections C and L 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

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

CVC does not own, manage, or operate any health service facilities in North Carolina.

In Section O.5, page 122, the applicant states that Carolina Vascular Care is not a licensed health service facility. 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.

C

The applicant proposes to develop a new ASF with no more than one dedicated vascular access operating room and one procedure room pursuant to the need determination in the 2023 SMFP.

In response to a petition, the State Health Coordinating Council approved an adjusted need determination for one dedicated vascular access OR in each of the six HSAs in the State. This application is to develop a new vascular access OR in HSA VI.

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- This proposal would develop one operating room by converting an OBL. The applicant projects sufficient surgical cases and hours to demonstrate the need for one operating room 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.