

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 26, 2024

Findings Date: January 26, 2024

Project Analyst: Cynthia Bradford

Co-Signer: Micheala Mitchell

Project ID #: J-12422-23

Facility: Triangle Vascular Care

FID #: 230723

County: Durham

Applicant(s): American Access Care of NC ASC, LLC.
AAC Management Services, LLC.

Project: Develop a new ASC in HSA IV with no more than one dedicated vascular access OR pursuant to the need determination in the 2023 SMFP and two procedure rooms.

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

American Access Care of NC ASC, LLC, and AAC Management Services, LLC (hereinafter referred to as “the applicant”) proposes to develop a new ASC in HSA IV with no more than one dedicated vascular access operating room pursuant to the need determination in the 2023 SMFP and two procedure rooms.

Need Determination

Chapter 6 of 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. Application of need methodology in the 2023 SMFP resulted in a need determination for two (2) ORs in Health Service Area (HSA) IV. However, 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 in the 2023 SMFP.

The applicant proposes to develop one dedicated vascular access OR with two procedure rooms in Durham County. Durham County is one of the counties within HSA IV. The applicant does not propose to develop more ORs than are approved to be developed. Therefore, the application is consistent with the need determination in the 2023 SMFP.

There are two policies in the 2023 SMFP which are applicable to this review: *Policy GEN-3 Basic Principles, and Policy GEN-4.*

Policy GEN-3 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.20 (a) and (d), pages 26-27, Section N, page 117, Section O, page 122, 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.20 (b) and (d), pages 26-27; Section C.6, page 65; Section L, page 108; Section N, page 118, 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.20 (c) and (d), page 27; Section K, pages 101-102, Section N, page 114; 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 pages 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 capital expenditure of the project is over \$5 million. In Section B, pages 27-28, the applicant describes its plan to ensure energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project’s plans to ensure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

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 ORs than are determined to be needed in the service area.
 - The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 because the applicant adequately demonstrates how its proposal incorporates the concepts of quality, equitable access, and maximum value for resources expended in meeting the need for the proposed services as identified by the applicant.
 - The applicant adequately demonstrates that the proposal is consistent with GEN-4 because 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 ASC in HSA IV with no more than one dedicated vascular access OR pursuant to the need determination in the 2023 SMFP and two procedure rooms.

Patient Origin

In Chapter 6 of the 2023 SMFP lists the health service facilities with licensed operating rooms. In Figure 6.1, page 53 of the 2023 SMFP, HSA IV is shown as a multicounty operating room service area. Thus, the service area for this facility consists of Chatham, Durham, Franklin, Granville, Johnston, Lee, Orange, Person, Vance, Wake and Warren counties. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 35, the applicant states that the applicant does not currently operate an ASC. The following summarizes historical patient origin for the existing Office Based Lab (OBL), i.e., Triangle Vascular Associates. The applicant provides the historical patient origin data for Triangle Vascular Associates cases performed by Stephen Loehr, MD, and William Pechter, MD, during the last full fiscal year 2022 and is summarized in the table below.

Triangle Vascular Associates Ambulatory Surgery Historical Patient Origin 01/01/2022 – 12/31/2022	
County	Patients
Chatham	10-49
Durham	100-489
Franklin	10-49
Granville	1-9
Johnston	100-489
Lee	10-49
Orange	10-49
Person	1-9
Vance	100-489
Wake	490-675
Warren	10-49
Total	842 to 2,405

In Section C, page 36, the applicant provides the Operating Room projected patient origin for the first three full fiscal years at Triangle Vascular Care, as summarized below.

Triangle Vascular Care Operating Room Projected Patient Origin FY2025-FY2027						
County	1st Full FY 1/1/2026-12/31/2026		2nd Full FY 1/1/2027-12/31/2027		3rd Full FY 1/1/2028-12/31/2028	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Wake	391	55.84%	418	55.84%	447	55.84%
Johnston	117	16.75%	125	16.75%	134	16.75%
Franklin	34	4.81%	36	4.81%	38	4.81%
Warren	6	0.91%	7	0.91%	7	0.91%
Durham	4	0.52%	4	0.52%	4	0.52%
Other NC counties & states^	148	21.17%	159	21.17%	169	21.17%
Total	699	100.0%	749	100.0%	800	100.0%

^Other includes patients from other NC counties and other states.

In Section C, page 36, the applicant provides the projected Procedure Room patient origin for the first three full fiscal years at Triangle Vascular Care, as summarized below.

Triangle Vascular Care Procedure Room Projected Patient Origin FY2025-FY2027						
County	1st Full FY 1/1/2026-12/31/2026		2nd Full FY 1/1/2027-12/31/2027		3rd Full FY 1/1/2028-12/31/2028	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Wake	632	27.86%	684	27.86%	738	27.86%
Johnston	86	3.77%	93	3.77%	100	3.77%
Vance	71	3.15%	77	3.15%	83	3.15%
Durham	65	2.86%	70	2.86%	76	2.86%
Franklin	32	1.41%	35	1.41%	37	1.41%
Orange	22	0.95%	23	0.95%	25	0.95%
Warren	19	0.83%	20	0.83%	22	0.83%
Chatham	13	0.58%	14	0.58%	15	0.58%
Lee	9	0.41%	10	0.41%	11	0.41%
Granville	8	0.37%	9	0.37%	10	0.37%
Person	8	0.37%	9	0.37%	10	0.37%
Other NC counties & states^	1,303	57.45%	1,411	57.45%	1,523	57.45%
Total	2,269	100.0%	2,457	100.0%	2,650	100.0%

^Other includes patients from other NC counties and other states.

In Section C, page 37, the applicant provides the combined projected Operating Room and Procedure Room patient origin for the first three full fiscal years at Triangle Vascular Care, as summarized below.

Triangle Vascular Care Operating Room and Procedure Room Projected Patient Origin FY2025-FY2027						
County	1st Full FY 1/1/2026-12/31/2026		2nd Full FY 1/1/2027-12/31/2027		3rd Full FY 1/1/2028-12/31/2028	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Wake	1,023	34.35%	1,103	34.35%	1,185	34.35%
Johnston	203	6.78%	218	6.78%	234	6.78%
Vance	71	2.42%	77	2.42%	83	2.42%
Durham	69	2.32%	74	2.32%	80	2.32%
Franklin	66	2.20%	71	2.20%	76	2.20%
Orange	25	0.85%	27	0.85%	29	0.85%
Warren	22	0.73%	23	0.73%	25	0.73%
Chatham	13	0.45%	14	0.45%	15	0.45%
Lee	9	0.31%	10	0.31%	11	0.31%
Granville	8	0.28%	9	0.28%	10	0.28%
Person	8	0.28%	9	0.28%	10	0.28%
Other NC counties & states^	1,451	49.03%	1,570	49.03%	1,692	49.03%
Total	2,968	100.0%	3,206	100.0%	3,451	100.0%

^Other includes patients from other NC counties and other states.

In Section C, pages 35 and 37, the applicant provides the assumptions and methodology used to project patient origin for Triangle Vascular Care. The applicant states that projected patient origin for the operating room and procedure rooms at Triangle Vascular Care is based on the FY2022 patient origin of procedures performed in its OBL at Triangle Vascular Associates.

The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant has experience providing the same service in the same service area.
- The applicant bases projected patient origin on the existing OBLs historical patient origin.

Analysis of Need

In Section C, pages 38-59, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 39, the applicant states the specific need for the project is based on the following factors:

- Increasing incidence of chronic kidney disease and End-Stage Renal Disease (pages 39-41)
- Changes in reimbursement for vascular access services which threaten the viability of OBLs (pages 41-42)
- Better quality, access, and cost-effectiveness of vascular access care in licensed ASF settings (pages 42-47)

- Faster acting, more effective anesthetics, and less invasive techniques have increased patient migration to outpatient services. ASFs provide more cost-effective vascular access care (pages 47-50)
- HSA IV is projected to increase its population by more than 200,000 residents during the next five years, with those aged 65+ projected to increase by 80,000 in the next five years (pages 50-59)

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

- The applicant provides reasonable information regarding the increase incidents of chronic kidney disease and end stage renal failure.
- The applicant provides reasonable information regarding the reimbursement cuts that have caused multiple OBL closures over the past five years.
- The applicant uses clearly cited and reasonable historical and projected population growth statistics for the HSA IV and historical service area population to be served and the continued demand for the services proposed.
- The applicant provides reasonable information to support HSA IV residents' need for access to high quality freestanding ASF services; and cites reasonable data demonstrating the cost-effectiveness of the proposal.

Projected Utilization

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

Triangle Vascular Care Projected Operating Room Utilization			
	1st Full FY 1/1/26-12/31/26	2nd Full FY 1/1/27-12/31/27	3rd Full FY 1/1/28-12/31/28
Operating Rooms			
Dedicated Ambulatory ORs	1	1	1
Total # of ORs	1	1	1
Adjusted Planning Inventory	1	1	1
Surgical Cases			
# of Outpatient Surgical Cases	981	999	1,016
Total # of Surgical Cases	981	999	1,016
Case Times (in hours)			
Outpatient	30.0	30.0	30.0
Surgical Hours			
Outpatient	491	499	508
Total Surgical Hours	491	499	508
# 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	0.37	0.38	0.39

In Section Q Form C.3b, pages 130-138, the applicant provides the assumptions and methodology used to project operating room utilization, as summarized below:

Step 1: The applicant states that Triangle Vascular Associates (TVA) existing OBL has one procedure room dedicated to vascular access needs of dialysis patients. The following table summarizes recent annual vascular access utilization for Triangle Vascular Care. The “procedure” column reflects the number of outpatient vascular access procedures performed during each calendar year as shown in the table below.

Triangle Vascular Associates Historical Utilization of Existing Procedure Room	
Year	Procedures
CY2019	3,455
CY2020	3,067
CY2021	3,039
CY2022	3,209
CY2023 YTD	1,438

Source: Section Q, page 131

The applicant projects utilization at Triangle Vascular Associates will increase by the weighted average population growth rate for the identified catchment area (1.77%) as shown on the following table.

Triangle Vascular Associates Projected Utilization of Existing Procedure Room	
Year	Procedures
CY2023^	3,451
CY2024	3,512
CY2025	3,574
CY2026	3,637
CY2027	3,702
CY2028	3,767

Source: Section Q, page 132

^ annualized based on Jan-May YTD

Step 2: The applicant projects utilization at Triangle Vascular Care (TVC) by assuming that during the initial three years of the project (CY26-CY28) that a percentage (75%-85%) of procedures will shift from the office-based TVA to the licensed TVC ambulatory surgical facility as shown on the following table.

Triangle Vascular Care Projected Utilization of Procedure Room shifted from TVA		
Year	Procedures	% Shift from TVA
CY2026	2,728	75%
CY2027	2,961	80%
CY2028	3,202	85%

Source: Section Q, pages 132-133

The applicant then projects 120 new fistula patients based on input from TVA physicians. For these new patents it is assumed that 75% of these patients will return for two follow up procedures. Of this group, 17.1% will receive stents, and 7.3% will receive thrombectomy. The projections of these procedures, combine with the projected shifts from TVA to TVC is shown in the table below.

Triangle Vascular Care Projected Utilization of Procedure Room		
Year	Procedures	% Shift from TVA
CY2026	2,968	75%
CY2027	3,205	80%
CY2028	3,450	85%

Source: Section Q, page 134

Step 3: The applicant projected TVC licensed operating room cases for CY2026 – CY2028 by as shown on the following table.

Triangle Vascular Care Projected Utilization of Operating Room Cases	
Year	Procedures
CY2026	699
CY2027	749
CY2028	800

Source: Section Q, page 135

The applicant then demonstrated conformity to the performance standards by using the projected OR cases for CY2026-CY2028 and applying the 2023 SMFP OR need methodology as shown in the following table.

Year	FY2026	FY2027	FY2028
Total OP Surgery Cases	699	749	800
Average Case Time (hours)	1.095	1.095	1.095
Total Surgical Hours	766	820	876
Group 6 Facility Standard Hours/OR	1,312	1,312	1,312
ORs Needed	0.58	0.63	0.67
ORs Needed (rounded)	1.0	1.0	1.0

Source: Section Q, page 135

Step 4: The applicant projected TVC licensed operating room cases for CY2026 – CY2028 as shown on the following table.

Triangle Vascular Care Projected Utilization of Operating Room Cases	
Year	Procedures
CY2026	2,269
CY2027	2,456
CY2028	2,650

Source: Section Q, page 136

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

- Projected utilization is based upon the historical OP procedures performed at Triangle Vascular Associates using internal data from the past four years.
- The applicant projects utilization at Triangle Vascular Care will increase by the weighted average population growth rate.
- Population projections and demographics support continued growth.
- The applicants considered the specialty surgical procedures to be offered at the proposed Triangle Vascular Care and projected utilization based on those specialties.
- Projected procedures in the proposed OR are based on historical data.

Access to Medically Underserved Groups

In Section C.6, page 65 the applicant states:

“All HSA IV residents (plus residents of other North Carolina counties), including low-income persons, racial and ethnic minorities, women, persons with disabilities, the elderly, Medicare and Medicaid beneficiaries, and any other underserved group, will have access to TVC, as clinically appropriate.”

On page 65, 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	13.4%
Racial and ethnic minorities	60.3%
Women	65.2%
Persons with disabilities	6.6%
Persons 65 and older	39.8%
Medicare beneficiaries	81.60%
Medicaid recipients	4.60%

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 has a history of providing services to low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

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.

CA

The applicant proposes to develop a new ASC in HSA IV with no more than one dedicated vascular access OR pursuant to the need determination in the 2023 SMFP and two procedure rooms.

In Section E.2, pages 74-77, 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 maintaining the status quo is not a viable option because an ASF is a more regulated, outpatient setting, thereby providing for optimal care and better clinical outcomes for the patient population.

- *Expand Triangle Vascular Associates Center* – The applicant states this is not an effective alternative because recent changes in reimbursement threaten the viability of OBLs. Therefore, the long-term viability of Triangle Vascular Associates is significantly threatened. The applicant also states that many ESRD patients requiring more complex are forced to go into a hospital setting. Adding additional rooms to TVA will not address this issue, therefore this is not a viable option in HSA IV.
- *Expand Raleigh Access Center* – The applicant states that this facility location is located in southeast Wake County which causes long travel times for the majority of the patient population in HSA IV, therefore this is not a viable option.
- *Utilize Existing Multi-Specialty Licensed Facilities in the Service Area*-The applicant states that it is often the case that physicians who perform vascular access procedures in an ED or hospital procedure room lack sufficient knowledge of ESRD patients and their vascular access history to make informed decisions about the most appropriate treatment options. For these reasons, outpatient vascular access facilities have been shown to provide patients with better outcomes and timelier, cost effective care than hospitals.
- *Develop the Proposed Diagnostic Center in Another Service Area Location* – The applicant states that although development of an ASF in other counties within the HSA IV would benefit the residents of that county, the fact that the medical infrastructure is concentrated in Durham County allows greater access to services to the overall patient population across the HSA IV service area.

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. American Access Care of NC ASC, LLC, and AAC Management Services, LLC, (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop one dedicated vascular access OR and two procedure rooms at Triangle Vascular Care.**

- 3. Upon project completion, Triangle Vascular Care shall be licensed for no more than one operating room and two procedure rooms.**
 - 4. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on March 1, 2024.**
 - 5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
 - 6. The certificate holder shall 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.

The applicant proposes to develop a new ASC in HSA IV with no more than one dedicated vascular access OR pursuant to the need determination in the 2023 SMFP and two procedure rooms.

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	\$4,526,500
Architect/Engineering	\$250,000
Medical Equipment	\$272,075
Non-Medical Equipment	\$70,000
Furniture	\$40,000
Consultant Fees	\$100,000
Other- Development Fee	\$349,055
Total	\$5,607,630

In Section F.3, In Section F, page 80, the applicant projects that start-up costs will be \$125,000 and initial operating expenses will be \$705,000 for a total working capital of \$830,000. 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 based on the following:

- The applicant identifies the costs included in the estimated start-up costs.
- The applicant bases its projections on its experience operating other ASCs.

Availability of Funds

In Section F.2, page 78, 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	AMERICAN ACCESS CARE OF NC ASC, LLC.	TOTAL
Loans	\$5,607,630	\$5,607,630
Accumulated reserves or OE*	\$0	\$0
Bonds	\$0	\$0
Other (funding from parent company)	\$0	\$0
Total Financing	\$5,607,630	\$5,607,630

In Section F, page 78, 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 August 10, 2023, from the Senior Vice President and Treasurer from National Medical Care Inc, documenting its intention to consider providing as much as \$7,000,000 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 based on the following:

- Exhibit F.2, the applicant the applicant provides a letter dated August 10, 2023, from the Senior Vice President and Treasurer from National Medical Care Inc, documenting its intention to consider providing as much as \$7,000,000 to cover all capital costs of the proposed project.

Financial Feasibility

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

TRIANGLE VASCULAR CARE OPERATING ROOM	1 ST FULL FISCAL YEAR 1/1/2026- 12/31/2026	2 ND FULL FISCAL YEAR 1/1/2027- 12/31/2027	3 RD FULL FISCAL YEAR 1/1/2028- 12/31/2028
Total OR Cases^	981	999	1,016
Total Gross Revenues (Charges)	\$14,053,519	\$15,352,730	\$16,730,413
Total Net Revenue	\$4,466,489	\$4,879,405	\$5,317,260
Average Net Revenue per Case^^	\$4,553	\$4,884	\$5,234
Total Operating Expenses (Costs)	\$2,124,165	\$2,268,227	\$2,422,351
Average Operating Expense per Case^^	\$2,165	\$2,270	\$2,384
Net Income	\$2,342,324	\$2,611,178	\$2,894,909

^Source: Section Q, Form F.2b and page 137

^^ May not sum due to rounding

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

TRIANGLE VASCULAR CARE PROCEDURE ROOMS	1 ST FULL FISCAL YEAR 1/1/2026- 12/31/2026	2 ND FULL FISCAL YEAR 1/1/2027- 12/31/2027	3 RD FULL FISCAL YEAR 1/1/2028- 12/31/2028
Total Procedure Cases^	2,891	2,942	2,994
Total Gross Revenues (Charges)	\$18,694,041	\$20,646,628	\$22,720,656
Total Net Revenue	\$6,066,964	\$6,700,657	\$7,373,762
Average Net Revenue per Case^^	\$2,098	\$2,278	\$2,463
Total Operating Expenses (Costs)	\$5,106,959	\$5,504,772	\$5,933,269
Average Operating Expense per Case^^	\$1,767	\$1,871	\$1,982
Net Income	\$960,005	\$1,195,884	\$1,440,493

^Source: Section Q, Form F.2b and page 137

^^ May not sum due to rounding

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, pages 139-145 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 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 ASC in HSA IV with no more than one dedicated vascular access OR pursuant to the need determination in the 2023 SMFP and two procedure rooms.

In Chapter 6 of the 2023 SMFP lists the health service facilities with licensed operating rooms. In Figure 6.1, page 53 of the 2023 SMFP, HSA IV is shown as a multicounty operating room service area. Thus, the service area for this facility consists of Chatham, Durham, Franklin, Granville, Johnston, Lee, Orange, Person, Vance, Wake and Warren counties. Facilities may also serve residents of counties not included in their service area.

HSA IV 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
Chatham Hospital	0	0	2	0	0	2	62	735
James E. Davis Ambulatory Surgical Center	0	4	0	0	0	4	0	5,137
Duke Ambulatory Surgery Center Arrington	0	4	0	0	2	6	0	131
Duke University Hospital*	6	9	50	-2	2	66	16,940	23,153
Duke Regional Hospital	2	0	13	-2	0	13	3,321	4,169
Southpoint Surgery Center	0	0	0	0	2	2	0	0
North Carolina Specialty Hospital	0	0	4	0	0	4	739	2,823
2021 SMFP Need Determination	0	0	0	0	2	2	0	0
Maria Parham-Franklin	0	0	3	0	-1	2	0	0
Same Day Surgery Center	0	0	0	0	2	2	0	0
Granville Health System	0	0	3	-4	0	3	473	2,077
UNC Health Johnston	2	0	8	-2	0	8	1,249	6,296
Central Carolina Hospital	1	0	6	-1	0	6	328	1,427
North Chapel Hill Surgery Center	0	0	0	0	2	2	0	0
University of North Carolina Hospitals	3	6	37	-5	11	52	13,111	17,419
Duke Health Orange Ambulatory Surgical Center	0	0	0	0	2	2	0	0
Person Memorial Hospital	1	0	4	-1	0	4	55	559
Duke Green Level Hospital	0	0	0	0	2	2	0	0
Duke Health Garner Ambulatory Surgical Center	0	0	0	0	1	1	0	0
Duke Health Green Level Ambulatory Surgery Center	0	0	0	0	1	1	0	0
Duke Health Raleigh Ambulatory Surgical Center	0	0	0	0	1	1	0	0
Duke Raleigh Hospital	0	0	15	0	-3	12	3,127	6,975
Orthopedic Surgery Center of Garner	0	0	0	0	1	1	0	0
Rex Surgery Center of Cary	0	4	0	0	0	4	0	3,522
Raleigh Orthopaedic Surgery Center	0	3	0	0	1	4	0	3,008
Rex Surgery Center of Wakefield	0	2	0	0	0	2	0	2,928
Raleigh Orthopedic Surgery Center West Cary	0	1	0	0	0	1	0	33
Rex Hospital	4	0	27	-4	1	28	7,388	13,646
WakeMed Surgery Center-Cary	0	0	0	0	1	1	0	0
WakeMed Surgery Center-North Raleigh	0	0	0	0	1	1	0	0
Capital City Surgery Center	0	8	0	0	-1	7	0	7,177
WakeMed	8	0	20	-5	0	23	8,300	13,287
WakeMed Cary Hospital	2	0	9	-2	1	10	2,759	4,417
OrthoNC ASC	0	0	0	0	1	1	0	0
RAC Surgery Center LLC	0	1	0	0	0	1	0	134
Surgical Center for Dental Professionals of NC LLC**	0	2	0	0	0	0	0	1,134
Blue Ridge Surgery Center	0	6	0	0	0	6	0	5,304
Raleigh Plastic Surgery Center	0	1	1	1	1	1	0	336
Valleygate Surgery Center	0	0	0	0	1	1	0	0

Triangle Surgery Center	0	2	2	0	1	3	0	2,821
Wake Spine and Specialty Surgery Center	0	0	0	0	1	1	0	0
Holly Springs Surgery Center	0	3	0	0	0	3	0	2,546
2022 SMFP Need Determination	0	0	0	0	2	2	0	0

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

** This is a dental single-specialty ambulatory surgery demonstration project that is in the inventory but is not included in need determination calculations.

In Section G.2, pages 89-90, 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:

“... the development of an ASF focused on vascular access and vascular treatment services would not unnecessarily duplicate hospital surgical capacity because 1) Vascular access maintenance procedures do not require a hospital setting and are mostly performed in physician offices now, and 2) dialysis access creation procedures are currently performed as an incidental part of hospitals’ broader surgical services and are often secondary to more emergent and clinically intensive surgeries.”

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.
- 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 IV.

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.

The applicant proposes to develop a new ASC in HSA IV with no more than one dedicated vascular access OR pursuant to the need determination in the 2023 SMFP and two procedure rooms.

In Section Q, Form H, page 146, the applicant provides projected full-time equivalent (FTE) positions for the proposed services, as summarized in the following table.

Triangle Vascular Care Center Projected FTE Positions			
Position	FY2025	FY2026	FY2027
Registered Nurses	7.5	7.5	7.5
Director of Nursing	1	1	1
Surgical Technicians	3	3	3
Radiology Technologists	3	3	3
Administrator/CEO	1	1	1
Clerical	3	3	3
Marketing Liaison	0.5	0.5	0.5
Medical Assistant	2	2	2
TOTAL	22.0	22.0	22.0

The assumptions and methodology used to project staffing are provided in Section Q, page 147. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3. In Section H.2, pages 92-93, the applicant describes Triangle Vascular Care's experience and process for recruiting and retaining staff and its proposed training and continuing education programs. The applicant provides adequate documentation of affiliations with clinical training programs in Exhibit M.1.

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 demonstrated adequate operating expenses for health manpower.
- The applicant has adequately demonstrated they have a process for the recruitment and hiring of qualified staff.
- The applicant has adequately demonstrated that they have appropriate affiliations with educational and medical institutions to provide clinical training to their employees.

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 ASC in HSA IV with no more than one dedicated vascular access OR pursuant to the need determination in the 2023 SMFP and two procedure rooms.

Ancillary and Support Services

In Section I.1, page 96, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 96-97, 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 HSA IV 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, pages 97-98, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant provides documentation of this in Exhibit I.2.2. The applicant also provides documentation of medical staff qualifications, and Medical Director credentials in Exhibits I.1.1, and I.1.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant has 25 years of experience serving the needs of kidney OR patients.
- 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. 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

In Section K, page 100, the applicant states that the project involves renovation of 7,530 square feet of existing space. Line drawings are provided in Exhibit K.1.

On pages 100-101, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal. A Medical Park Drive Lease LOI and marketing brochure are provided in Exhibit K.4.

On page 101, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On pages 101-102, 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

Triangle 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 106, the applicant provides the historical payor mix during the last full fiscal year (1/1/22 to 12/31/22) for vascular access services provided at their OBL, as shown in the following table:

TRIANGLE VASCULAR Associates HISTORICAL PAYOR MIX LAST FULL FY2022	
PAYOR CATEGORY	% OF TOTAL
Self-Pay	2.3%
Charity Care	0.5%
Medicare*	69.0%
Medicaid*	4.4%
Insurance*	23.8%
Total	100.0%

*Including any managed care plans.

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

Triangle Vascular Care FY2022	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY DURING THE LAST FULL FY
Female	65.2%
Male	34.8%
Unknown	0.0%
64 and Younger	60.22%
65 and Older	39.78%
American Indian	0.41%
Asian	0.97%
Black or African-American	50.79%
Native Hawaiian or Pacific Islander	0.06%
White or Caucasian	36.85%
Other Race	3.03%
Declined / Unavailable	7.89%

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;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 108, 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 109, 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 because TVC is not an existing facility.

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 110, 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:

TRIANGLE VASCULAR CARE PROJECTED PAYOR MIX 3 RD FULL FY2028	
PAYOR CATEGORY	% OF TOTAL
Self Pay	2.83%
Medicare*	68.77%
Medicaid*	4.37%
Insurance*	24.03%
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 68.77% of total surgical services in the OR will be provided to Medicare patients and 4.37% to Medicaid patients.

In Section L, page 109 the applicant states that the projected payor mix is based on the CY2022 payor mix for vascular access patients at Triangle Vascular Care.

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, pages 111-112, 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 ASC in HSA IV with no more than one dedicated vascular access OR pursuant to the need determination in the 2023 SMFP and two procedure rooms.

In Section M, page 113, 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 have access to the facility for training purposes based on the following:

- The applicant has existing relationships and clinical training agreements with Wake Forest Baptist Medical Center Department of Radiology, Diagnostic Radiology Residency.

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 ASC in HSA IV with no more than one dedicated vascular access OR pursuant to the need determination in the 2023 SMFP and two procedure rooms.

In Chapter 6 of the 2023 SMFP lists the health service facilities with licensed operating rooms. In Figure 6.1, page 53 of the 2023 SMFP, HSA IV is shown as a multicounty operating room service area. Thus, the service area for this facility consists of Chatham, Durham, Franklin, Granville, Johnston, Lee, Orange, Person, Vance, Wake and Warren counties. Facilities may also serve residents of counties not included in their service area.

HSA IV 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
Chatham Hospital	0	0	2	0	0	2	62	735
James E. Davis Ambulatory Surgical Center	0	4	0	0	0	4	0	5,137
Duke Ambulatory Surgery Center Arrington	0	4	0	0	2	6	0	131
Duke University Hospital*	6	9	50	-2	2	66	16,940	23,153
Duke Regional Hospital	2	0	13	-2	0	13	3,321	4,169
Southpoint Surgery Center	0	0	0	0	2	2	0	0
North Carolina Specialty Hospital	0	0	4	0	0	4	739	2,823
2021 SMFP Need Determination	0	0	0	0	2	2	0	0
Maria Parham-Franklin	0	0	3	0	-1	2	0	0
Same Day Surgery Center	0	0	0	0	2	2	0	0
Granville Health System	0	0	3	-4	0	3	473	2,077
UNC Health Johnston	2	0	8	-2	0	8	1,249	6,296
Central Carolina Hospital	1	0	6	-1	0	6	328	1,427
North Chapel Hill Surgery Center	0	0	0	0	2	2	0	0
University of North Carolina Hospitals	3	6	37	-5	11	52	13,111	17,419
Duke Health Orange Ambulatory Surgical Center	0	0	0	0	2	2	0	0
Person Memorial Hospital	1	0	4	-1	0	4	55	559
Duke Green Level Hospital	0	0	0	0	2	2	0	0
Duke Health Garner Ambulatory Surgical Center	0	0	0	0	1	1	0	0
Duke Health Green Level Ambulatory Surgery Center	0	0	0	0	1	1	0	0
Duke Health Raleigh Ambulatory Surgical Center	0	0	0	0	1	1	0	0
Duke Raleigh Hospital	0	0	15	0	-3	12	3,127	6,975
Orthopedic Surgery Center of Garner	0	0	0	0	1	1	0	0
Rex Surgery Center of Cary	0	4	0	0	0	4	0	3,522
Raleigh Orthopaedic Surgery Center	0	3	0	0	1	4	0	3,008
Rex Surgery Center of Wakefield	0	2	0	0	0	2	0	2,928
Raleigh Orthopedic Surgery Center West Cary	0	1	0	0	0	1	0	33
Rex Hospital	4	0	27	-4	1	28	7,388	13,646
WakeMed Surgery Center-Cary	0	0	0	0	1	1	0	0
WakeMed Surgery Center-North Raleigh	0	0	0	0	1	1	0	0
Capital City Surgery Center	0	8	0	0	-1	7	0	7,177
WakeMed	8	0	20	-5	0	23	8,300	13,287
WakeMed Cary Hospital	2	0	9	-2	1	10	2,759	4,417
OrthoNC ASC	0	0	0	0	1	1	0	0
RAC Surgery Center LLC	0	1	0	0	0	1	0	134
Surgical Center for Dental Professionals of NC LLC**	0	2	0	0	0	0	0	1,134
Blue Ridge Surgery Center	0	6	0	0	0	6	0	5,304
Raleigh Plastic Surgery Center	0	1	1	1	1	1	0	336
Valleygate Surgery Center	0	0	0	0	1	1	0	0

Triangle Surgery Center	0	2	2	0	1	3	0	2,821
Wake Spine and Specialty Surgery Center	0	0	0	0	1	1	0	0
Holly Springs Surgery Center	0	3	0	0	0	3	0	2,546
2022 SMFP Need Determination	0	0	0	0	2	2	0	0

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

** This is a dental single-specialty ambulatory surgery demonstration project that is in the inventory but is not included in need determination calculations.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 114, the applicant states:

“... The proposed project will increase access to care without negatively impacting existing providers in the service area. In short, the Durham ASF project will represent a new opportunity for HAS IV residents to access vascular access outpatient surgical services more conveniently located to their home.”

Regarding the impact of the proposal on cost-effectiveness, in Section N, page 115, the applicant states:

“This OR project will not increase the charges or projected reimbursement for services, which are established by Medicare, Medicaid, and/or existing private payor contracts.”

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

Regarding the impact of the proposal on quality, in Section N, page 117, the applicant states:

“...TVC will be licensed by the State of North Carolina, certified for participation in Medicare and Medicaid, and will be accredited by the Joint Commission (TJC).”

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:

“... As a certified provider under Title XVIII (Medicare) and Title XIX (Medicaid), TVC will provide its services to the elderly and low income persons.”

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.

C

In Section Q, Form O, page 148, the applicant identifies two ASFs located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O.5, page 123, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. According to the files in the Acute and Home Care Licensure Section, DHRS, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure Section and considering the quality of care provided at all three facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department

shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The applicant proposes to develop a new ASC in HSA IV with no more than one dedicated vascular access OR pursuant to the need determination in the 2023 SMFP and two procedure rooms.

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 IV.

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.
- (b) *The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.*
- C- In Section Q, Form C, pages 137-138, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.