

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: July 28, 2023

Findings Date: July 28, 2023

Project Analyst: Cynthia Bradford

Co-Signer: Lisa Pittman

Project ID #: G-12352-23

Facility: CK Vascular Center

FID #: 230309

County: Guilford

Applicant(s): Carolina Kidney Associates, PA

Project: Develop one dedicated vascular access OR in HSA II pursuant to the 2023 SMFP need determination

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 Kidney Associates, PA or CKA (hereinafter referred to as “the applicant”) proposes to develop one new vascular access OR pursuant to the 2023 SMFP adjusted need determination for a total of one vascular access OR upon project completion.

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 II.

There is one policy in the 2023 SMFP which are applicable to this review: *Policy GEN-3 Basic Principles. 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 (a) and (d), pages 26-27, Section N.2, page 85 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 26-27; Section C.6, pages 46-47; Section L, pages 81-82; Section N.2, page 86, 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; Section F, pages 58-64; Section K, pages 75-76, Section N, page 85; 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.

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 Guilford County.
 - The applicant adequately documents how the project will promote equitable access to operating room services in Guilford 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.

(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 one new vascular access OR pursuant to the 2023 SMFP adjusted need determination for a total of one vascular access OR upon project completion.

In Section C.1, page 28, the applicant states that,

“CKA operates a vascular access office-based laboratory (OBL) with one procedure room in Guilford County. The facility, Carolina Kidney Vascular Access Center (CK Vascular), opened in 2012 and is located in Greensboro, NC 27455. The proposed project will convert CKA Vascular existing procedure room to a licensed OR and establish a single specialty ASC.”

Patient Origin

On page 48, the 2023 SMFP states, “Counties with at least one facility having a licensed OR that are not grouped with another county are single county service areas. A multicounty service area is created under two conditions: 1) counties without a facility with a licensed OR are grouped with the single county where the largest proportion of its patients received surgery; 2) if two counties with at least one facility having a licensed OR each provided surgical services to at least 35 percent of the residents of a county without at least one facility with a licensed OR, then the county without at least one facility with a licensed OR is grouped with both of the counties with facilities that have at least one OR.”

In Figure 6.1, page 53 of the 2023 SMFP, Guilford County is shown as a multicounty operating room service area. Thus, the service area for this facility consists of Guilford County and Caswell County. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 30, the applicant states that CKA does not currently operate an ASC. The following summarizes historical patient origin for the existing Office Based Lab (OBL), i.e., CK Vascular. The applicant provides the historical patient origin data for CK Vascular cases performed in CK Vascular during the last full fiscal year 2022 and is summarized in the table below.

CK Vascular Ambulatory Surgery Historical Patient Origin 1/1/2022 to 12/31/2022		
County	Patients	% of Total
Guilford	483	72.0%
Rockingham	75	11.2%
Randolph	74	11.0%
Alamance	8	1.1%
Other^	31	4.7%
Total	670	100.0%

^Other includes less than 1% of patients from remaining NC counties

In Section C, page 31, the applicant provides the projected patient origin for the first three full fiscal years at CK Vascular, as summarized below.

CK Vascular 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
Guilford	491	72.0%	494	72.0%	497	72.0%
Rockingham	76	11.2%	77	11.2%	77	11.2%
Randolph	75	11.0%	76	11.0%	76	11.0%
Alamance	8	1.1%	8	1.1%	8	1.1%
Other NC Counties	32	4.7%	32	4.7%	32	4.7%
Total	682	100.0%	686	100.0%	691	100.0%

^Other includes less than 1% of patients from other NC counties and other states.

In Section C, pages 31 and 34, the applicant provides the assumptions and methodology used to project patient origin for CK Vascular. The applicant states that projected patient origin for the operating room and procedure rooms at CK Vascular is based on the FY2022 patient origin of procedures performed in its OBL at CK Vascular.

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 32-41, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 32, the applicant states the specific need for the project is based on the following factors:

- Changes in reimbursement for vascular access services provided in OBLs (pages 33-35)
- Historical utilization of CK Vascular (pages 36-37)
- Need for cost-effective access to vascular access services (page 37)
- Service area demographics (pages 37-41)

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

- The applicant provides reasonable information regarding the reimbursement cuts that have created multiple OBL closures over the past five years.

- The applicant cites current utilization data to illustrate that their current utilization of vascular procedure could support three vascular ORs in their service area based on 2023 SMFP criteria.
- The applicant uses clearly cited and reasonable historical and projected population growth statistics for the Guilford County and historical service area population to be served and the continued demand for the services proposed.
- The applicant provides reasonable information to support Guilford County 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 CK Vascular for the first three full fiscal years upon project completion, as illustrated in the following table.

CK Vascular Projected OR Utilization			
	1st Full FY 1/1/25-12/31/25	2nd Full FY 1/1/26-12/31/26	3rd Full FY 1/1/27-12/31/27
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	1,181	1,188	1,196
Total # of Surgical Cases	1,181	1,188	1,196
Case Times (in hours)			
Outpatient	65.7	65.7	65.7
Surgical Hours			
Outpatient	1,294	1,301	1,309
Total Surgical Hours	1,294	1,301	1,309
# 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	1.0	1.0	1.0

In Section Q Form C.3b, pages 93-94, the applicant provides the assumptions and methodology used to project operating room utilization, as summarized below:

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

CK Vascular Historical Utilization of Existing Procedure Room		
Year	Procedures	Cases
CY2019	1,581	1,252
CY2020	1,439	1,139
CY2021	1,651	1,307
CY2022	1,466	1,161

Source: Section Q, page 93

Step 2: The applicant projects utilization at CK Vascular will increase by the weighted average population growth rate for the identified catchment area (0.6%) as shown on the following table.

CK Vascular Projected Utilization of Proposed OR/ Procedure Room			
Year	Procedures	Cases	Patients Served
CY2023	1,475	1,168	674
CY2024	1,483	1,174	678
CY2025	1,492	1,181	682
CY2026	1,501	1,188	686
CY2027	1,510	1,196	691

Source: Section Q, page 94

In Section Q, Page 94, the applicant states,

“During CY2022, CKA’s dialysis patients experienced an average of 1.7 annual encounters per patient at CK Vascular. CKA anticipates the same ratio of annual cases per patient through the third project year. The following table summarizes the projected number of patients served at CK Vascular.”

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

- Projected utilization is based upon the historical OP surgery utilization at CK Vascular using internal data from the past four years.
- The applicant projects utilization at CK Vascular 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 CK Vascular 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 46 the applicant states:

“All individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will continue to have access to CK Vascular’ vascular access services, as clinically appropriate. CK Vascular does not and will not discriminate based on race, ethnicity, age, gender, or disability.”

On page 47, 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	14%
Racial and ethnic minorities	73%
Women	44%
Persons with disabilities	*
The elderly	50%
Medicare beneficiaries	84%
Medicaid recipients	4%

*Applicant does not track this data

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:

- CK Vascular 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
- Information publicly available during the review and used by the Agency

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

- (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 one new vascular access OR pursuant to the 2023 SMFP adjusted need determination for a total of one vascular access OR upon project completion.

In Section E.2, pages 56-57, 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 an effective alternative because recent changes in reimbursement threaten the viability of OBLs. Therefore, the long-term viability of CK Vascular is significantly threatened. The applicant determined this is not the most effective alternative.
- *Utilize Existing 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 more timely and cost effective care than hospitals.

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 Kidney Associates, PA (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 ambulatory surgery facility at CK Vascular Center.**
- 3. Upon project completion, CK Vascular Center 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 December 1, 2023.**
- 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 one new vascular access OR pursuant to the 2023 SMFP adjusted need determination for a total of one vascular access OR upon project completion.

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	\$1,273,339
Architect/Engineering	\$42,000
Consultant Fees	\$50,000
Financing Costs	\$10,000
Interest During Construction	\$20,000
Other- Contingency	\$25,000
Total	\$1,420,339

In Section Q, page 102, the applicants provide the assumptions used to project the capital cost.

In Section F.3, page 60, the applicant states that the project involves converting an existing OBL to an ASC, thus, there are no start up or initial operating expenses associated with the project.

The applicant adequately demonstrates that the projected capital costs of the project are based on reasonable and adequately supported assumptions based on the following:

- Renovation costs are based on the experience of CKA with similar projects.

Availability of Funds

In Section F.2, page 58, 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 Kidney Associates, PA	TOTAL
Loans	\$1,420,339	\$1,420,339
Accumulated reserves or OE*	\$0	\$0
Bonds	\$0	\$0
Other (funding from parent company)	\$0	\$0
Total Financing	\$1,420,339	\$1,420,339

In Section F, page 58, 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 April 5, 2023, from the Market President, for American National Bank & Trust Company documenting its intention to consider providing as much as \$1,420,339 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 provides a letter dated April 5, 2023, from the Market President, for American National Bank & Trust Company documenting its intention to consider providing as much as \$1,420,399 to cover all capital costs of the proposed project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, page 97, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	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 [^]	1,181	1,188	1,196
Total Gross Revenues (Charges)	\$2,975,235	\$3,022,814	\$3,071,154
Total Net Revenue	\$1,725,636	\$1,753,232	\$1,781,269
Average Net Revenue per Case ^{^^}	\$1,461	\$1,476	\$1,489
Total Operating Expenses (Costs)	\$1,692,184	\$1,713,795	\$1,735,183
Average Operating Expense per Case ^{^^}	\$1,433	\$1,443	\$1,451
Net Income	\$33,453	\$39,437	\$46,087

[^]Source: Section Q, pages 94 and 97

^{^^} 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, page 102 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 one new vascular access OR pursuant to the 2023 SMFP adjusted need determination for a total of one vascular access OR upon project completion.

On page 50, the 2023 SMFP states, “*Counties with at least one facility having a licensed OR that are not grouped with another county are single county service areas.*” In Figure 6.1, page 53 of the 2023 SMFP, Guilford County is shown as a multicounty operating room service area. Thus, the service area for this facility consists of Guilford County and Caswell County. 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 Guilford County, and the inpatient and outpatient case volumes for each provider, from pages 58 and 70 of the 2023 SMFP.

Guilford 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
High Point Surgery Center	0	6	0	0	0	6	0	3,671
Premier Surgery Center	0	2	0	0	0	2	0	1,174
High Point Regional Health	3	0	8	-1	0	10	2,328	3,601
Atrium Health Total	3	8	8	-1	0	18		
North Elam Ambulatory Surgery Center	0	0	0	0	5	5	0	0
Cone Health	4	13	29	-1	-5	40	10,404	16,570
Moses H. Cone Memorial Hospital Total	4	13	29	-1	0	45		
Greensboro Specialty Surgical Center	0	3	0	0	0	3	0	1,305
Surgical Center of Greensboro	0	13	0	0	0	13	0	10,831
Surgical Care Affiliates Total	0	16	0	0	0	16		
Valleygate Dental Surgery Center of the Triad^^	0	2	0	0	0	0	0	1,608
Surgical Eye Center	0	4	0	0	0	4	0	3,044
Piedmont Surgical Center	0	2	0	0	0	2	0	0
Kindred Hospital - Greensboro	0	0	1	0	0	1	174	14
Total Guilford/ Caswell Total	7	45	38	-2	-1	86		

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 the need determination calculations.

In Section G.2, page 67, 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:

“ASCs in Guilford County do not offer vascular access services. If ASCs were to offer vascular access procedures, dialysis patients would have to compete with the availability of block times for multiple other physician specialties. Patients would not have the same level of access to vascular access services as they do at CK Vascular.”

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 II.

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 one new vascular access OR pursuant to the 2023 SMFP adjusted need determination for a total of one vascular access OR upon project completion.

In Section Q, Form H, page 100, the applicant provides projected full-time equivalent (FTE) positions for the proposed services, as summarized in the following table.

CK Vascular Center Projected FTE Positions			
Position	FY2025	FY2026	FY2027
Registered Nurses	2.0	2.0	2.0
Radiology Technologists	2.0	2.0	2.0
Clerical	1.0	1.0	1.0
Manager	1.0	1.0	1.0
TOTAL	6.0	6.0	6.0

The assumptions and methodology used to project staffing are provided in Section Q, page 104. 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 69-70, the applicant describes CK Vascular'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 the area and is a significant employer in Guilford 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 one new vascular access OR pursuant to the 2023 SMFP adjusted need determination for a total of one vascular access OR upon project completion.

Ancillary and Support Services

In Section I.1, page 71, the applicant identifies the necessary ancillary and support services for the proposed services. On page 71, 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 Guilford 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 72, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant has 40 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.

- (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:
- would be available under a contract of at least 5 years duration;
 - would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - would cost no more than if the services were provided by the HMO; and
 - 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 75, the applicant states that the project involves renovation of 6,108 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 76, 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.

On page 76, 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 page 76, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

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

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

CK Vascular 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 79, 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:

CK VASCULAR HISTORICAL PAYOR MIX LAST FULL FY2022	
PAYOR CATEGORY	% OF TOTAL
Medicare*	84%
Medicaid*	4%
Insurance*	7%
TriCare	4%
Other (Gov't)	1%
Total	100.0%

*Including any managed care plans.

In Section L, page 80, the applicant provides the following comparison:

CK Vascular Center FY2022	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	44%	53%
Male	55%	47%
Unknown		
64 and Younger	50%	16%
65 and Older	50%	84%
American Indian		
Asian	3%	6%
Black or African-American	68%	36%
Native Hawaiian or Pacific Islander	<1%	0.1%
White or Caucasian	27%	55%
Other Race		3%
Declined / Unavailable	1.5%	

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 80, 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 81, 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 81, 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:

CK VASCULAR PROJECTED PAYOR MIX 3RD FULL FY2027	
PAYOR CATEGORY	% OF TOTAL
Medicare*	84%
Medicaid*	4%
Insurance*	7%
TriCare	4%
Other (Gov't)	1%
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 84% of total surgical services in the OR will be provided to Medicare patients and 4% to Medicaid patients.

In Section L, page 81 the applicant states that the projected payor mix is based on the CY2022 payor mix for vascular access patients at CK Vascular.

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 82, 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 one new vascular access OR pursuant to the 2023 SMFP adjusted need determination for a total of one vascular access OR upon project completion.

In Section M, page 84, 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 East Carolina University and Cone Health.
- The applicant provides a copy of the clinical training agreements with East Carolina University and Cone Health for APP Fellowship Placements 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 one new vascular access OR pursuant to the 2023 SMFP adjusted need determination for a total of one vascular access OR upon project completion.

On page 50, the 2023 SMFP states, “Counties with at least one facility having a licensed OR that are not grouped with another county are single county service areas.” In Figure 6.1, page 53 of the 2023 SMFP, Guilford County is shown as a multicounty operating room service area. Thus, the service area for this facility consists of Guilford County and Caswell County. 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 Guilford County, and the inpatient and outpatient case volumes for each provider, from pages 58 and 70 of the 2023 SMFP.

Guilford 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
High Point Surgery Center	0	6	0	0	0	6	0	3,671
Premier Surgery Center	0	2	0	0	0	2	0	1,174
High Point Regional Health	3	0	8	-1	0	10	2,328	3,601
Atrium Health Total	3	8	8	-1	0	18		
North Elam Ambulatory Surgery Center	0	0	0	0	5	5	0	0
Cone Health	4	13	29	-1	-5	40	10,404	16,570
Moses H. Cone Memorial Hospital Total	4	13	29	-1	0	45		
Greensboro Specialty Surgical Center	0	3	0	0	0	3	0	1,305
Surgical Center of Greensboro	0	13	0	0	0	13	0	10,831
Surgical Care Affiliates Total	0	16	0	0	0	16		
Valleygate Dental Surgery Center of the Triad^^	0	2	0	0	0	0	0	1,608
Surgical Eye Center	0	4	0	0	0	4	0	3,044
Piedmont Surgical Center	0	2	0	0	0	2	0	0
Kindred Hospital - Greensboro	0	0	1	0	0	1	174	14
Total Guilford/ Caswell Total	7	45	38	-2	-1	86		

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 the need determination calculations.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 85, the applicant states:

“The proposed project will positively impact competition. The proposed project is a logical and responsible approach by CKA to ensure continued access to critically necessary, lifesaving vascular access services for dialysis patients.”

Regarding the impact of the proposal on cost-effectiveness, in Section N, page 85, the applicant states:

“This project will not affect the cost to patients or payors for the services provided by CK Vascular because reimbursement rates are set by the federal government and

commercial insurers. The capital expenditure for this project is necessary to ensure that CK Vascular will continue to provide high-quality services that are accessible to patients.”

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 85-86, the applicant states:

“The proposed project will promote safety and quality in the delivery of vascular access services. CK Vascular is committed to the provision of comprehensive, high quality, safe, and cost-effective vascular access services to persons in need of such services.”

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 86, the applicant states:

“CK Vascular has existing strategies with specific activities designed to assure services will be accessible by indigent patients without regard to ability to pay. CK Vascular will not discriminate in the provision of services on the basis of age, race, religion, disability, or the patient’s ability to pay.”

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

In Section Q, Form O, page 101, the applicant states that CK Vascular is an existing OBL. CKA does not own, manage, or operate any health service facilities in North Carolina.

In Section O.5, page 88, the applicant states that CK Vascular 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 one new vascular access OR pursuant to the 2023 SMFP adjusted need determination for a total of one vascular access OR upon project completion.

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 II.

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.