

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 24, 2023

Findings Date: March 3, 2023

Project Analyst: Tanya M. Saporito

Co-Signer: Micheala M. Mitchell

Project ID #: M-12270-22

Facility: Cape Fear Valley Medical Center

FID #: 943057

County: Cumberland

Applicant(s): Cumberland County Hospital System, Inc.

Project: Develop a hospital-based outpatient 4-station dialysis facility pursuant to Policy ESRD-3

### 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

Cumberland County Hospital System, Inc., hereinafter referred to as “the applicant” proposes to develop no more than four dialysis stations pursuant to Policy ESRD-3 to provide hospital-based outpatient dialysis services on the third floor of Cape Fear Valley Medical Center (CFVMC), an existing acute care hospital in Fayetteville. The patients proposed to be served do not include home hemodialysis or peritoneal dialysis patients.

#### **Need Determination**

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2022 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

## **Policies**

There is one policy on pages 22-23 in the 2022 SMFP applicable to this review: *Policy ESRD-3: Development or Expansion of a Kidney Disease Treatment Center on a Hospital Campus* states:

*“Licensed acute care hospitals (see stipulations in G.S. 131E-77 (e1)) may apply for a certificate of need to develop or expand an existing Medicare-certified kidney disease treatment center (outpatient dialysis facility) without regard to a county or facility need determination if all the following are true:*

- 1. The hospital proposes to develop or expand the facility on any campus on its license where general acute beds are located.*
- 2. The hospital must own the outpatient dialysis facility, but the hospital may contract with another legal entity to operate the facility.*
- 3. The hospital must document that the patients it proposes to serve in an outpatient dialysis facility developed or expanded pursuant to this policy are inappropriate for treatment in an outpatient dialysis facility not located on a hospital campus.*
- 4. The hospital must establish a relationship with a community-based outpatient dialysis facility to assist in the transition of patients from the hospital outpatient dialysis facility to a community-based facility wherever possible.*

*The hospital shall propose to develop at least the minimum number of stations allowed for Medicare certification by the Centers for Medicare and Medicaid Services (CMS). Certificate of need will impose a condition requiring the hospital to document that it has applied for Medicare certification no later than three (3) years from the effective date on the certificate of need.*

*The performance standards in 10A NCAC 14C .2203 do not apply to a proposal submitted by a hospital pursuant to this policy.”*

In Section B.6, pages 17-18 and in supplemental information provided to the Agency, the applicant explains why it believes its application is consistent with Policy ESRD-3 summarized as follows:

- The proposed project involves the development of an outpatient dialysis services to be located on the third floor of CFVMC, an existing acute care hospital with 500 acute care beds.
- The applicant states the hospital currently provides dialysis services via a service agreement. The hospital has recently experienced an increase in the number of patients who could benefit from outpatient dialysis services in the hospital until placement in a community-based dialysis center.
- Since the dialysis services will be provided in the main campus of CFVMC, the applicant will own the facility in which dialysis services will be provided.

- The applicant documents that the patients proposed to be served are inappropriate for treatment in an outpatient dialysis facility not located on a hospital campus. On page 18 the applicant defines these patients as:
  - Patients who admit to the emergency department in urgent need of dialysis, who must be admitted as an inpatient in order to receive dialysis.
  - Patients referred to the hospital from dialysis facilities because of missed appointments at their regular dialysis center.
  - Patients with medical complications.
  - Patients with behavioral health issues
  - Patients with no payor source
  - Patients who present to the hospital requiring dialysis and must be admitted as an observation or inpatient to be dialyzed by the inpatient dialysis program until they can receive treatment at a dialysis facility.
- The applicant documents its relationship with Fresenius Medical Care for the provision of dialysis services to CFVMC's patients. In supplemental information requested by the Agency, the applicant provides a September 6, 2022 letter from the Regional Vice President, Eastern NC Region of Fresenius Kidney Care that confirms Fresenius Kidney Care's intent to provide dialysis services to CFVMC's patients on temporary, interim and emergency bases and to transition those patients to existing community-based ESRD facilities.

### **Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion. The applicant adequately demonstrates that the proposal is consistent with Policy ESRD-3 based on the following:

- The applicant adequately demonstrates a plan to develop outpatient dialysis services on the third floor of the existing acute care hospital.
- The applicant adequately demonstrates it owns the facility within which dialysis services will be provided.
- The applicant adequately demonstrates that the patients proposed to be served are inappropriate for treatment in an outpatient dialysis facility not located on a hospital campus.
- The applicant adequately demonstrates it has a relationship with a dialysis provider in the service area and documents the dialysis provider's support in transitioning patients to community dialysis services in the area when appropriate.

- (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 no more than four dialysis stations pursuant to Policy ESRD-3 to provide hospital-based outpatient dialysis services on the third floor of Cape Fear Valley Medical Center (CFVMC), an existing acute care hospital in Fayetteville.

In Section C, pages 18-19, the applicant provides a brief description of the proposed project. The applicant states:

*“CFVMC does not intend to supplant community-based outpatient dialysis facilities. CFVMC already maintains long-standing relationships with community-based dialysis facilities and will work with them to assist in the transition of patients from the hospital-based outpatient dialysis facility to a community-based facility whenever possible.*

...

*CFVMC proposes to develop a Medicare-certified kidney disease treatment center (outpatient dialysis facility) with four (4) stations pursuant to Policy ESRD-3. CFVMC will acquire four (4) hemodialysis machines and (4) recliners, which will be located on the 3<sup>rd</sup> floor of the main hospital. ... CFVMC will enter into a Service Agreement with Fresenius to provide outpatient dialysis treatments at the proposed outpatient dialysis facility.”*

**Patient Origin**

On page 115, the 2022 SMFP defines the service area for dialysis stations as “*the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” CFVMC is located in Cumberland County. Thus, the service area for this facility consists of Cumberland County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 20, the applicant states that the proposed project involves the development of a new facility, therefore, there is no historical patient origin to report.

The following table, from Section C page 21, illustrates projected patient origin:

**CFVMC Projected Patient Origin  
 Inpatient Dialysis Services**

COUNTY	2 <sup>ND</sup> FULL FY OF OPERATION FOLLOWING PROJECT COMPLETION 10/1/2024-9/20/2025	
	PATIENTS	% OF TOTAL
Cumberland	853	84.1%
Harnett	59	
Hoke	34	5.8%
Bladen	20	3.3%
Robeson	11	1.9%
Sampson	6	1.1%
Other	31	0.6%
<b>Total</b>	<b>1,014</b>	<b>100.0%</b>

Source: Application page 21.

In Section C, page 21, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant bases projected patient origin on its FY 2021 inpatient dialysis patient origin.
- The applicant states using historical inpatient dialysis utilization because it states a portion of the inpatient dialysis patients are expected to utilize the proposed outpatient dialysis services.

**Analysis of Need**

In Section C, pages 24-30, the applicant explains why it believes the population projected to utilize the proposed dialysis services needs the proposed services, as summarized below:

- Service area demographics – The applicant utilized data from the North Carolina Office of State Budget and Management (NCOSBM) to project population growth in the service area. The applicant states the population as a whole is projected to increase by a compound annual growth rate (CAGR) of 0.3% between 2022-2026, and the 65+ cohort is projected to increase by a CAGR of 2.3% during the same time. The applicant states the incidence of ESRD and other diseases and conditions that contribute to a diagnosis of ESRD increase with a person’s age (pages 24-25).
- Race and Ethnicity in the service area – The applicant researched data provided by the United Health Foundation and determined that the prevalence of chronic kidney disease is higher among African Americans and Hispanic adults when compared with Caucasian and Asian adults. The applicant cites the US Census Bureau’s findings that approximately 39.8% of Cumberland County residents are Black or African American which, when compared to the state as a whole, is higher [approximately 13.6% of the

state's population is Black or African American]. Thus, the demographic composition of Cumberland County contributes to the need for dialysis services (pages 25-26).

- Disease prevalence and incidence – The applicant cites the Centers for Disease Control and Prevention (CDC) and the North Carolina State Center for Health Statistics and states the two disease processes that present the greatest risk for developing ESRD are diabetes and hypertension. The applicant states Cumberland County and the surrounding counties that are included in the proposed service area have a higher incidence of both diabetes and hypertension than other counties in the state, which is indicative of the need for dialysis services in the area (pages 27-28).
- Need for outpatient dialysis services on the CFVMC campus – The applicant states it has historically provided inpatient dialysis services via an inpatient services agreement with Fresenius Kidney care to its patients in need of dialysis services. Additionally, the applicant states there are many outpatients routinely referred to the hospital for dialysis for a number of reasons, such as a patient who requires regular dialysis and is admitted to the hospital as an inpatient. The applicant examined its historical data regarding emergency and outpatients who received dialysis treatment while at the hospital. The applicant states the three-year CAGR from FY 2019-FY 2022 was 15.8% for emergency patients and 27.8% for outpatients in need of dialysis services. The applicant states the addition of outpatient dialysis services at the hospital will result in improved access to dialysis services and enhanced care for its patients in need of dialysis services (pages 28-30).

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

- The applicant provides reliable data that shows projected population growth in the service area, particular those 65 and over who tend to utilize more health resources, including ESRD services.
- The applicant provides reliable data to show the incidence of diseases and conditions in the populations that comprise the service area that lead to end stage renal disease.
- The applicant's proposal is in response to its experience with ESRD patients who have historically presented to CFVMC in need of dialysis services and for whom treatment in a community-based facility is inappropriate.
- The applicant relies on growth trends and historical utilization of its existing inpatient dialysis unit to justify its need for the proposal.

#### Projected Utilization

In Section Q, page 42, the applicant provides a table to illustrate projected utilization for the first two years of operation, FYs 2024 and 2025 (10/1-9/30), as shown below:

IN-CENTER DIALYSIS PATIENTS	1 <sup>ST</sup> FULL FY (FFY 2024)	2 <sup>ND</sup> FULL FY (FFY 2025)
Average # Pts During the Year	989	1,014
# Treatments/Pt/Year	1.46	1.46
<b>Total # Treatments</b>	<b>1,449</b>	<b>1,484</b>

In Section Q, pages 74-77, the applicant provides the assumptions and methodology used to project utilization, as summarized below:

Step 1: Review historical CFVMC patients appropriate for hospital-based outpatient dialysis

Relying on its internal data, the applicant identified the number of historical dialysis patients previously dialyzed on the hospital's inpatient dialysis equipment who could appropriately be treated as outpatients at the hospital from FY 2019-FY 2022 (annualized at the time the application was prepared). The applicant categorized these patients into three groups: emergency, outpatients, and inpatients awaiting discharge. The applicant determined that emergency patients who could appropriately be treated as outpatients in the hospital's proposed outpatient dialysis services increased by a CAGR of 15.8%, and the outpatients who could be similarly treated increased by a CAGR of 27.8% during those years. See the table that illustrates the calculations on page 74.

Step 2: Project hospital's hemodialysis patients to be treated at the proposed outpatient dialysis facility

The applicant projected the number of hemodialysis patients in both groups (emergency and outpatients) projected to be served at CFVMC's proposed outpatient dialysis facility by applying one-third of the historical CAGR in each group to the annualized FY 2022 patient numbers through FY 2025, the applicant's third project year. The group "inpatients awaiting discharge" was held constant through the three project years, because the applicant states they do not have the means to identify the number of inpatients held for discharge while waiting for placement in community-based outpatient dialysis centers and the number is an estimate based on discussions with medical staff and clinical leadership. See the table that illustrates these projections on page 75. The applicant states the projections are reasonable based on its study of the service area demographics and population (pages 74-75).

Step 3: Determine the number of dialysis treatments to be performed

Relying on its internal data, the applicant examined the historical number of dialysis treatments per patient for the groups it identified in Step 1 for the same time period: FY 2019-FY 2022. The applicant did not include the group "inpatients awaiting discharge" to a community-based dialysis facility for the reasons identified in Step 2. The applicant applied the FY 2022 year to date annualized number of treatments per patient (1.46) to the projected number of patients deemed appropriate for the proposed outpatient dialysis facility from Step 2. See the table that illustrates these projections on page 77.

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

- The applicant’s utilization projections are supported by the historical utilization of ESRD patients determined to be appropriate for the proposed outpatient dialysis facility.
- The applicant provides reliable data regarding the health status of the population proposed to be served and the increasing need for dialysis services in that population.
- The applicant provides reliable data to support the projected incremental increase in projections.

**Access to Medically Underserved Groups**

In Section C, page 32, the applicant states:

*“At CFVMC all services are available to all patients upon the request of physicians with appropriate privileges, regardless of race, sex, income status, ability to pay, disability, age, or other underserved characteristics. ...*

*Low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups, [sic] will have access to the proposed services at CFVMC.”*

On page 33, the applicant provides the estimated percentage for each medically underserved group as shown in the following table:

MEDICALLY UNDERSERVED GROUPS	PERCENTAGE OF TOTAL PATIENTS DURING THE 2ND FFY
Low income persons	14.5%
Racial and ethnic minorities	48.9%
Women	50.4%
Persons with disabilities	*
Persons 65 and older	75.7%
Medicare beneficiaries	75.7%
Medicaid recipients	12.8%

\*The applicant states on page 33 that CFVMC does not maintain data regarding the number of disabled persons it serves.

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 its historical experience with the provision of dialysis services to its patients and the demographic makeup of the service area.

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

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

CA

The applicant proposes to develop no more than four dialysis stations pursuant to Policy ESRD-3 to provide hospital-based outpatient dialysis services on the third floor of Cape Fear Valley Medical Center (CFVMC), an existing acute care hospital in Fayetteville..

In Section E, page 40, the applicant describes the one alternative it considered and explains why that alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternative considered was:

Maintain the Status Quo – The applicant states it has identified specific patient cohorts that cannot be treated at community-based outpatient dialysis centers, thus indicating a need for inpatient dialysis services at the hospital. If the applicant chose not to develop the proposed outpatient dialysis facility, those patient cohorts would require dialysis as an inpatient at the hospital. That is not an effective alternative because it utilizes inpatient services that could better serve the hospital’s inpatients. Additionally, it would result in undue stress to those patients from having to be admitted to the hospital simply to receive dialysis services.

On page 40, the applicant states that its proposal will not compete with or replace existing community-based dialysis facilities but will work with those facilities to effectively transition patients to those facilities when appropriate.

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

- The proposed project will reduce emergency department visits and avoid patients receiving necessary dialysis services in inappropriate settings.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Cumberland County Hospital System, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application and any supplemental responses. If representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. Pursuant to Policy ESRD-3, the certificate holder shall develop a new Medicare-certified kidney disease treatment center (outpatient dialysis facility) with no more than four in-center dialysis stations at Cape Fear Valley Medical Center upon project completion.**
- 3. Pursuant to Policy ESRD-3, the certificate holder shall document that it has applied for Medicare certification no later than three (3) years from the effective date on the certificate of need.**
- 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 August 1, 2023.**

**5. 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 no more than four dialysis stations pursuant to Policy ESRD-3 to provide hospital-based outpatient dialysis services on the third floor of Cape Fear Valley Medical Center (CFVMC), an existing acute care hospital in Fayetteville.

**Capital and Working Capital Costs**

In Section Q, page 78, the applicant projects the total capital cost of the project as shown in the following table:

<b>CAPE FEAR VALLEY MEDICAL CENTER (OUTPATIENT DIALYSIS CENTER) CAPITAL COSTS</b>	
Medical Equipment	\$151,400
Non-Medical Equipment	\$57,000
Furniture	\$18,600
Consultant Fees	\$40,000
Other (Contingency)	\$83,000
<b>Total</b>	<b>\$350,000</b>

In Section Q, page 84, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant provides documented quotes for equipment costs in Exhibit C.1.
- The applicant included a contingency for unforeseen renovation costs that may occur.
- There are no financing costs since the project will be funded with cash reserves.
- The applicant included in its estimation of equipment costs dialysis chairs and miscellaneous equipment such as IV pumps, glucose machines, crash carts and vital signs machines.

In Section F, page 43, the applicant states that there will be no start-up or initial operating costs because it will enter into a Hospital Services Agreement with Fresenius Kidney Care for the provision of dialysis services and Fresenius Kidney Care will provide the necessary plumbing and other equipment as well as clinical staff for the project.

**Availability of Funds**

In Section F, page 42, the applicant states that the capital cost will be funded as shown in the table below:

**Sources of Capital Cost Financing**

TYPE	CAPE FEAR VALLEY HEALTH SYSTEM	TOTAL
Loans	\$0	\$0
Accumulated reserves or OE *	\$350,000	\$350,000
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$350,000</b>	<b>\$350,000</b>

\* OE = Owner's Equity

Exhibit F.2 contains a letter dated September 1, 2022 from the Chief Financial Officer for Cape Fear Valley Health System that confirms the availability of sufficient accumulated reserves for the capital needs of the project. The Exhibit also contains the audited financial statements for Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Health System that show a total of \$502,300,000 in total current assets and \$317,933,000 in cash and cash equivalents as of September 30, 2021.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the applicant's documentation of sufficient accumulated reserves and the applicant's willingness to commit the necessary funds to the project.

**Financial Feasibility**

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

MISSION HOSPITAL OUTPATIENT DIALYSIS CENTER	1 <sup>ST</sup> FULL FY FY 2023	2 <sup>ND</sup> FULL FY FY 2024
Total Patients		
Total Gross Revenues (Charges)	\$1,051,266	\$1,109,651
Total Net Revenue	\$425,763	\$449,409
Average Net Revenue per Treatment	\$430	\$443
Total Operating Expenses (Costs)	\$422,639	\$437,419
Average Operating Expense per Treatment	\$427	\$431
Net Income	\$3,124	\$11,990

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, page 85. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant accounts for projected operating expenses, such as salaries, consistent with projections elsewhere in the application.
  - Charges are based on anticipated reimbursement by payor and include 3% increases annually.
  - Contractual rates are based on anticipated reimbursement by payor and the applicant’s experience providing inpatient dialysis.
  - Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- (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 no more than four dialysis stations pursuant to Policy ESRD-3 to provide hospital-based outpatient dialysis services on the third floor of Cape Fear Valley Medical Center (CFVMC), an existing acute care hospital in Fayetteville.

On page 115, the 2022 SMFP defines the service area for dialysis stations as *“the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.”* Thus, the service area for this facility consists of Cumberland County. Facilities may also serve residents of counties not included in their service area.

The following table lists the existing and approved dialysis facilities, certified stations, and utilization in Cumberland County as of December 31, 2020, as illustrated in Table 9A of the 2022 SMFP:

<b>Cumberland County Dialysis Facilities</b>				
FACILITY NAME	CERTIFIED STATIONS AS OF 12/31/2020	# OF IC PATIENTS AS OF 12/31/2020	UTILIZATION BY PERCENT AS OF 12/31/2020	PATIENTS PER STATION
Fayetteville Kidney Center	56	167	74.55%	2.98
FMC Dialysis Services North Ramsey	40	152	95.00%	3.80
FMC Dialysis Services South Ramsey	47	163	86.70%	3.47
FMC Dialysis Services of West Fayetteville	40	173	108.13%	4.33
Fresenius Kidney Care Hope Mills (new)	0	0	0.00%	0.00
Fresenius Kidney Care Rockfish	25	68	68.00%	2.72
<b>Total</b>	<b>208</b>	<b>723</b>	<b>73.48%</b>	<b>3.48</b>

Source: 2022 SMFP, Table 9A, page 123

In Section G, page 49, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Cumberland County. The applicant states:

*“CFVMC proposes to develop an outpatient dialysis facility pursuant to SMFP Policy ESRD-3. CFVMC will be the first hospital-based outpatient dialysis center in Cumberland County. ... The proposed project will not unnecessarily duplicate existing community-based outpatient dialysis centers because CFVMC intends to serve patients than cannot be treated by existing community-based outpatient dialysis centers.”*

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

- The proposal represents the only hospital-based outpatient dialysis facility in Cumberland County.
- The proposal will not result in an increase in hospital-based outpatient dialysis centers or community-based dialysis centers.
- The applicant intends to work with patients and Fresenius Kidney Care to transition patients to community-based dialysis centers when appropriate.
- The applicant adequately demonstrates that the proposed dialysis services are needed in addition to the existing or approved dialysis services.

### **Conclusion**

The Agency reviewed the:

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

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

- (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 no more than four dialysis stations pursuant to Policy ESRD-3 to provide hospital-based outpatient dialysis services on the third floor of Cape Fear Valley Medical Center (CFVMC), an existing acute care hospital in Fayetteville.

In Section Q, page 82, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

POSITION	PROJECTED FTE	
	STAFF	
	1 <sup>ST</sup> FULL FY FY 2024	2 <sup>ND</sup> FULL FY FY 2025
Housekeeping	0.1	0.1
<b>Total</b>	<b>0.1</b>	<b>0.1</b>

The assumptions and methodology used to project staffing are provided in Section Q, page 85. The applicant states Fresenius will provide clinical staff. Adequate operating expenses for the positions proposed by the applicant are budgeted in F.4. In Section H, pages 50-51, the applicant describes the methods used to recruit or fill new positions and its existing 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:

- CFVMC has an established history of recruiting and retaining clinical and non-clinical personnel.
- CFVMC has an established orientation and training program specific to each position.
- CFVMC requires clinical staff members to attend continuing education programs on a regular and continuing basis.

**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.

- (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 no more than four dialysis stations pursuant to Policy ESRD-3 to provide hospital-based outpatient dialysis services on the third floor of Cape Fear Valley Medical Center (CFVMC), an existing acute care hospital in Fayetteville.

In Section I, page 52, the applicant identifies the necessary ancillary and support services for the proposed hospital-based dialysis services. On page 52, 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 CFVMC's existing clinical ancillary and support services that are currently in place to support existing services.

### **Coordination**

In Section I, page 53, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- CFVMC has established a relationship with Womack Army Medical Center in which Cape Fear Valley Health System has identified and responded to growing medical needs for active-duty military family members.
- CFVMC works closely with the Cumberland County Health Department and other safety net providers in Cumberland and nearby counties to provide patient care.
- CFVMC has an existing inpatient agreement with Fresenius Kidney Care for patient dialysis care.

### **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.

- (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.

NA

The applicant does not propose to construct any new space, renovate any existing space nor make minor renovations to existing space.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and persons with disabilities, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
  - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

NA

Neither the applicant nor any related entities own, operate or manage an existing outpatient dialysis facility located in the service area. Therefore, Criterion (13a) is not applicable to this review.

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 61, the applicant states it is not obligated under any applicable federal regulations to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 61, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and 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 61, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the following table:

<b>CFVMC PROJECTED PAYOR MIX, FFY 2025</b>		
<b>PRIMARY PAYOR SOURCE AT ADMISSION</b>	<b># OF PATIENTS</b>	<b>IN-CENTER DIALYSIS SERVICES AS PERCENT OF TOTAL</b>
Self-Pay	17	1.7%
Insurance*	28	2.8%
Medicare*	768	75.7%
Medicaid*	130	12.8%
Other (VA, Tricare)	72	7.0%
<b>Total</b>	<b>1,014</b>	<b>100.0%</b>

\*Including managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.7% of total services will be provided to self-pay patients, 75.7% to Medicare patients and 12.8% to Medicaid patients.

On page 61, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the most recent historical data for CFVMC's inpatient dialysis 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 based on the reasons stated above.

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

C

In Section L, page 62, 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 no more than four dialysis stations pursuant to Policy ESRD-3 to provide hospital-based outpatient dialysis services on the third floor of Cape Fear Valley Medical Center (CFVMC), an existing acute care hospital in Fayetteville.

In Section M, pages 64-66, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes. The applicant

adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- CFVMC currently has health professional training programs in place. The applicant states it is highly accessible to area schools and training programs, which will continue following project completion.
- The applicant states it currently partners with the Cumberland County school system to provide students opportunities to meet Certified Nursing requirements beginning in high school.
- The applicant offers health professional training programs in many clinical areas and will continue the clinical rotations following project completion.

### **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.

- (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 no more than four dialysis stations pursuant to Policy ESRD-3 to provide hospital-based outpatient dialysis services on the third floor of Cape Fear Valley Medical Center (CFVMC), an existing acute care hospital in Fayetteville.

On page 115, the 2022 SMFP defines the service area for dialysis stations as *“the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and*

*Yancey counties.*” Thus, the service area for this facility consists of Cumberland County. Facilities may also serve residents of counties not included in their service area.

The following table lists the existing and approved dialysis facilities, certified stations, and utilization in Cumberland County as of December 31, 2020, as illustrated in Table 9A of the 2022 SMFP:

<b>Cumberland County Dialysis Facilities</b>				
FACILITY NAME	CERTIFIED STATIONS AS OF 12/31/2020	# OF IC PATIENTS AS OF 12/31/2020	UTILIZATION BY PERCENT AS OF 12/31/2020	PATIENTS PER STATION
Fayetteville Kidney Center	56	167	74.55%	2.98
FMC Dialysis Services North Ramsey	40	152	95.00%	3.80
FMC Dialysis Services South Ramsey	47	163	86.70%	3.47
FMC Dialysis Services of West Fayetteville	40	173	108.13%	4.33
Fresenius Kidney Care Hope Mills (new)	0	0	0.00%	0.00
Fresenius Kidney Care Rockfish	25	68	68.00%	2.72
<b>Total</b>	<b>208</b>	<b>723</b>	<b>73.48%</b>	<b>3.48</b>

Source: 2022 SMFP, Table 9A, page 123

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 68, the applicant states:

*“... CFVMC does not intend to supplant or compete with community-based outpatient dialysis facilities. CFVMC already maintains long-standing relationships with community-based dialysis facilities and will work with them to assist in the transition of patients from the hospital-based outpatient dialysis facility to a community-based facility whenever possible.*

*... the proposed project will foster competition by continuing to promote cost effectiveness, quality, and access to dialysis services in the service area.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 68, the applicant states:

*“The proposed project will promote cost effectiveness in several ways. The development of an outpatient dialysis facility at DFVMC is intended to reduce the costs associated with the delivery of dialysis services on the hospital campus.”*

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 68-69, the applicant states:

*“The project provides a safe outpatient setting for emergency patients needing immediate access to dialysis treatment. The project also ensures access to outpatient dialysis service for patients who are awaiting placement at a community-based outpatient treatment*

*facility. The proposed outpatient dialysis facility will adhere to all of CFVMC's quality standards as well as all applicable licensure standards."*

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 69, the applicant states:

*"CFVMC has existing strategies with specific activities designed to assure services will be accessible by indigent patients without regard to ability to pay. CFVMC 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 Section 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
- Information publicly available during the review and used by the Agency

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

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

C

In Section Q, page 83, the applicant identifies the hospital located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of six hospitals located in North Carolina.

In Section O, page 71, the applicant states that, during the 18 months immediately preceding the submittal of the application, one incident related to quality of care occurred at CFVMC on February 24, 2022 that resulted in an immediate jeopardy. The applicant states it submitted a plan of correctio to NC DHSR and the immediate jeopardy was lifted. As of May 4, 2022 the facility was back in full compliance with the plan of correction. After reviewing and considering information provided by the applicant and considering the quality of care provided at this facility, 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.

NA

The applicant proposes to develop no more than four dialysis stations pursuant to Policy ESRD-3 to provide hospital-based outpatient dialysis services on the third floor of Cape Fear Valley Medical Center (CFVMC), an existing acute care hospital in Fayetteville. There are no administrative rules that are applicable to proposals for a hospital-based, outpatient dialysis center pursuant Policy ESRD-3.