

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: August 13, 2021

Findings Date: August 13, 2021

Project Analyst: Ena Lightbourne

Team Leader: Fatimah Wilson

Project ID #: G-12079-21

Facility: Renal Care Group-Caswell

FID #: 960925

County: Caswell

Applicant(s): Renal Care Group of the South, Inc.

Project: Relocate no more than two dialysis stations from BMA Burlington pursuant to Policy ESRD-2 for a total of no more than 17 stations upon project completion

### 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

Renal Care Group of the South, Inc. (hereinafter referred to as “the applicant”), proposes to relocate no more than two dialysis stations pursuant to Policy ESRD-2 from BMA of Burlington (BMA Burlington) to Renal Care Group-Caswell (“RCG Caswell”) for a total of no more than 17 stations upon project completion.

#### **Need Determination**

Chapter 9 of the 2021 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9D, page 138, the county need methodology shows there is no county need determination for additional dialysis stations in Caswell County. The applicant is proposing to relocate existing dialysis stations; therefore, the facility need methodology does

not apply to this proposal. Therefore, neither of the two need determination methodologies in the 2021 SMFP apply to this proposal.

**Policies**

There is one policy in the 2021 SMFP that is applicable to this review: Policy ESRD-2: Relocation of Dialysis Stations.

Policy ESRD-2: Relocation of Dialysis Stations, on page 21 of the 2021 SMFP, states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:*

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina State Medical Facilities Plan, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina State Medical Facilities Plan.”*

The following table illustrates the applicant’s proposal to relocate dialysis stations to a contiguous county.

Line 1	County that will gain stations		Caswell
Line 2	Projected station deficit for the County identified in Line 1		8
		<b>Contiguous County 1</b>	<b>Contiguous County 2</b>
Line 3	Facility losing stations or moving to a contiguous county	BMA Burlington	
Line 4	County that will lose stations	Alamance	
Line 5	Projected stations surplus for County identified on Line 4	29	
Line 6	Number of stations to be relocated or moved from the facility identified on Line 3	-2	
Line 7	Subtract Line 6 from Line 5	27	
Line 8	Number of residents of the county identified in Line 1 that were dialyzing at the facility identified on Line 3	1	

Source: Section B, page 19

The applicant proposes to relocate existing dialysis stations from BMA Burlington in Alamance County to RCG Caswell in Caswell County. According to December 2020 ESRD Data Collection Forms submitted to the Agency, BMA of Burlington in Alamance County was serving two patients residing in Caswell County. Table 9B of the 2021 SMFP, states that Alamance County had a surplus of 29 stations and Caswell County had a deficit of eight stations. Therefore, the application is consistent with Policy ESRD-2.

### **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 the application is conforming to this criterion based on the following:

- Neither the county nor facility need methodology is applicable to this review.
- The applicant adequately demonstrates that the application is consistent with Policy ESRD-2 based on the following:
  - The applicant proposes to relocate two dialysis stations to Caswell County from a contiguous county.
  - The facility losing stations is currently serving residents of Caswell County.
  - The proposal will not result in an increase in an existing deficit in the number of dialysis station in the county losing stations nor will it result in an increase in an existing surplus of dialysis stations in the county that is gaining stations.

- (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 relocate no more than two dialysis stations pursuant to Policy ESRD-2 from BMA Burlington to RCG Caswell for a total of no more than 17 stations upon project completion.

On page 113, the 2021 SMFP defines the service area for dialysis stations as “*the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Caswell County. Facilities may also serve residents of counties not included in their service area.

According to December 2020 ESRD Collection Forms submitted to the Agency, RCG Caswell does not currently serve home hemodialysis or peritoneal dialysis patients. The following table illustrates historical and projected patient origin.

<b>RCG Caswell Historical and Projected Patient Origin</b>				
<b>County</b>	<b>Historical 01/01/2020-12/31/2020 (CY 2020)</b>		<b>Second Full FY of Operation following Project Completion 01/01/2024-12/31/2024 (CY 2024)</b>	
	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>
Caswell	30	78.9%	47.4	78.9%
Alamance	2	5.3%	2.0	5.3%
Orange	1	2.6%	1.0	2.6%
Virginia	5	13.2%	5.0	13.2%
<b>Total</b>	<b>38</b>	<b>100.0%</b>	<b>55.4</b>	<b>100.0%</b>

Source: Section C, pages 23-24

In Section C, pages 23-24, 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 begins projections of the future patient population to be served with RCG Caswell’s facility census as of December 31, 2020.
- The applicant projects that the relocated stations will be certified as of December 31, 2022. Therefore, Operating Year 1 (OY1) is Calendar Year (CY) 2023, January 1-December 31, 2023 and Operating Year 2 (OY2) is Calendar Year (CY) 2024, January 1-December 31, 2024.
- The applicant projects growth of the Caswell County patient census using the Five-Year average Annual Change Rate (AACR) of 12.1%, as published in the 2021 SMFP.
- The applicant projects that the facility will continue to serve the eight in-center patients residing in Alamance and Orange Counties and Virginia, which are contiguous to Caswell County. The applicant assumes these patients will continue their dialysis treatment with the facility and does not project any growth for this segment of the patient population. The applicant states that these patients will be added to projections of future patient populations at the appropriate time.

**Analysis of Need**

In Section C, page 27, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 27, the applicant states:

- The applicant states that as the ESRD patient population of the county increases, more dialysis stations are needed.
- The applicant projects a utilization rate of 73.91%, or 2.96 patients per station as of the end of the first operating year of the project, which exceeds the minimum required by the performance standard.

- The relocation of two dialysis stations will reduce the eight-station deficit to six stations and will help ensure continued convenient access to dialysis care for the ESRD patients of Caswell County.

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

- The applicant uses the 2021 SMFP Caswell County Five-Year AACR to project a utilization rate of 73.91%, or 2.96 patients per station as of the end of the first operating year.
- The applicant’s proposal will reduce the eight-station deficit in Caswell County to six stations.

Projected Utilization

In Section C, page 26 and Section Q, page 85, the applicant provides projected utilization, as illustrated in the following table.

<b>RCG Caswell</b>	
Begin with the Caswell County patient population as of December 31, 2020.	30
Project the Caswell County patient population forward for one year to December 31, 2021, using the Caswell County Five-Year AACR.	$30 \times 1.121 = 33.6$
Add the eight patients from Alamance and Orange Counties and Virginia.	$33.6 + 8 = 41.6$
Project the Caswell County patient population Forward for one year to December 31, 2022, using the Caswell County Five-Year AACR.	$33.6 \times 1.121 = 37.7$
Add the eight patients from Alamance and Orange Counties and Virginia. This the project starting census for this project.	$37.7 + 8 = 45.7$
Project the Caswell County patient population forward for one year to December 31, 2023, using the Caswell County Five-Year AACR.	$37.7 \times 1.121 = 42.3$
Add the eight patients from Alamance and Orange Counties and Virginia. This the project ending census for Operating Year 1.	$42.3 + 8 = 50.3$
Project the Caswell County patient population forward for one year to December 31, 2024, using the Caswell County Five-Year AACR.	$42.3 \times 1.121 = 47.4$
Add the eight patients from Alamance and Orange Counties and Virginia. This the project ending census for Operating Year 2.	$47.4 + 8 = 55.4$

The applicant projects to serve 50.3 in-center patients in OY1 and 55.4 in-center patients in OY2. Thus, the applicant projects that RCG Caswell will have a utilization rate of 73.91% or 2.96 patients per station per week ( $50.3 \text{ patients} / 17 \text{ stations} = 2.96 / 4 = 0.74$  or 74%) in OY1. The projected utilization of 2.96 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant begins projections of the future patient population to be served with the facility census as of December 31, 2020.
- The applicant projects growth using the 2021 SMFP Caswell County Five-Year AACR.
- The applicant projects that the facility will continue to serve the eight in-center patients residing in Alamance and Orange Counties and Virginia. The applicant assumes these patients will continue to dialysis with facility and does not project any growth for this segment of the patient population.
- The utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

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

In Section C, page 30, the applicant states:

*“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.*

...

*It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or health insurer.”*

The applicant provides the estimated percentage for each medically underserved group during the 2<sup>nd</sup> operating year, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low income persons	100.00%
Racial and ethnic minorities	81.08%
Women	35.14%
Persons with Disabilities	54.05%
Persons 65 and older	62.16%
Medicare beneficiaries	97.30%
Medicaid recipients	2.70%

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:

- Fresenius Medical Care related facilities have history of providing services to low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.
- The applicant’s estimated percentage for each underserved group is based upon RCG Caswell’s recent experience.

**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.

C

The applicant proposes to relocate no more than two dialysis stations pursuant to Policy ESRD-2 from BMA Burlington to RCG Caswell for a total of no more than 17 stations upon project completion.

The following table shows the projected number of stations at BMA Burlington upon project completion. In Project ID# G-11737-19, the applicant proposed to relocate 12 stations from BMA Burlington to the BMA of South Greensboro facility. The application was approved to relocate only 10 of the 12 stations. That decision was subsequently appealed. In Section D, page 36, the applicant states that if the Agency’s decision is upheld, BMA Burlington will have 33 stations upon approval of this application.

<b>BMA Burlington</b>		
County where the facility is located		Alamance
1	Total number of existing, approved, and proposed dialysis stations as of the application deadline	45
2	Number of existing dialysis stations to be reduced, relocated or eliminated in this proposal	-2
3	Total number of dialysis station upon completion of this project and all other projects involving this facility	33

Source: Section D, page 36

In Section D, pages 36-37, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated or relocate will be adequately met following completion of the project. The applicant states that the needs of the patients continuing to use the BMA Burlington facility will not be affected by the approval of this application, regardless of the Court’s decision on Project ID# G-11737-19. The applicant states that the proposed relocation is scheduled to be completed December 31, 2022. The applicant

assumes that the appeal will be in its favor to relocate the 12 stations initially proposed, thus, the applicant's projections of BMA Burlington's future utilization is based on the facility having 31 stations to serve 100.1 in-center patients; a utilization rate of 3.03 patients per station per week. However, upon completion of this project and Project ID# G-11737-19 (relocate 10 stations) the facility will have 33 stations; a projected utilization rate of 3.23 patients per station per week.

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

- The applicant based its future projected utilization on the facility having 33 stations upon completion of this project and Project # G-11737-19 (relocate 10 stations).
- The applicant projects a utilization rate by the end of OY1 that is above the minimum standard of 2.8 patients per station per week if the facility is approved to relocate the two additional stations.

In Section D, page 37, the applicant provides projected utilization, as illustrated in the following table.

<b>BMA Burlington</b>		
	<b>Alamance</b>	<b>Guilford</b>
Begin with the respective county in-center patient population as of December 31, 2020.	65	2
Project the patient population forward for one year to December 31, 2021, using the County Five Year AACR.	$65 \times 1.03 = 67.0$	$26 \times 1.04 = 27.0$
Add the patients from Caswell and Orange Counties. This is the projected year end census for 2021.	$67.0 + 27.0 + 3 = 97.2$	
Project the patient population forward for one year to December 31, 2022.	$67.0 \times 1.03 = 69.0$	$27.0 \times 1.04 = 28.1$
Add the patients from Caswell and Orange Counties. This is the projected year end census for 2022.	$69.0 + 28.1 + 3 = 100.1$	

The applicant projects to serve 100.1 in-center patients on 33 stations as of the date the stations are projected to be relocated. Thus, the applicant projects that BMA Burlington will have a utilization rate of 0.7583% or 3.03 patients per station per week ( $100.1 \text{ patients} / 33 \text{ stations} = 3.03 / 4 = 0.7583$  or 75.83%).

In Section D, page 37, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant projects that the relocated stations will be certified as of December 31, 2022.
- The applicant begins projections of the future patient population served by the BMA Burlington facility as of December 31, 2020.
- The applicant projects growth of the Alamance County patient census using the Alamance County AACR of 3.0%, as published in Table 9B of the 2021 SMFP.



- According to the December 2020 ESRD Data Collection Forms submitted to the Agency, 26 in-center patients were residing in Guilford County. The applicant projects growth of this segment of the patient population using the Guilford County Five-Year AACR of 4.0%, as published in the 2021 SMFP.
- The applicant projects that the facility will continue to serve the three in-center patients residing in Caswell and Orange Counties which are contiguous to Alamance County. The applicant assumes these patients will continue to dialysis with facility and does not project any growth for this segment of the patient population. The applicant states that these patients will be added to projections of future patient populations at the appropriate time.

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

- The applicant begins projections of the future patient population served by the BMA Burlington facility as of December 31, 2020.
- The applicant projects growth using the 2021 SMFP County Five-Year AACR for Alamance and Guilford Counties, respectively.
- The applicant projects that the facility will continue to serve the three in-center patients residing in Caswell and Orange Counties and does not project any growth for this segment of the patient population.
- The utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

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

In Section D, page 38, the applicant states:

*Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.*

...

*It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or health insurer."*

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use dialysis services will be adequately met based on the history of Fresenius Medical Care related facilities providing services to all persons in need of dialysis services, including those defined as medically underserved.

### **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 the following reasons:

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

- (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 relocate no more than two dialysis stations pursuant to Policy ESRD-2 from BMA Burlington to RCG Caswell for a total of no more than 17 stations upon project completion.

In Section D, page 41, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo-The applicant states that not applying for additional stations at RCG Caswell would result in higher utilization rates. The applicant projects that utilization on 15 stations would be 3.4 patients per station at the end of OY1 and 3.7 patient per station at the end of OY2.

Relocate Fewer than Two Stations-The applicant states that this is not an effective alternative because of the projected higher utilization rates.

Apply for more than Two Stations-The applicant states that this is not a cost-effective alternative. The facility does not have space for more than 17 stations.

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 applicant addresses the issue of higher utilization rates as the facility patient census increases.
- 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. Renal Care Group of the South, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, the certificate holder shall relocate no more than 2 in-center stations (and home hemodialysis) stations from BMA of Burlington to Renal Care Group-Caswell for a total of no more than 17 in-center stations upon project completion.**
- 3. Upon completion of this project and Project ID# G-11737-19 (add 10 stations), the certificate holder shall take the necessary steps to decertify 2 in-center stations (and home hemodialysis) stations at BMA of Burlington for a total of no more than 33 in-center and home hemodialysis stations at BMA of Burlington.**
- 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. Progress reports shall be due on the first day of every Fourth month. The first progress report shall be due on June 1, 2022. The second progress report shall be due on October 1, 2022 and so forth.**
- 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 relocate no more than three dialysis stations pursuant to Policy ESRD-2 from DRI Burlington to RCG Caswell for a total of no more than 17 stations upon project completion.

**Capital and Working Capital Costs**

In Section Q, page 89, the applicant projects the total capital cost of the project, as shown in the table below.

<b>RCG Caswell Capital Costs</b>	
Non-Medical Equipment	\$1,500
Furniture	\$6,000
<b>Total</b>	<b>\$7,500</b>

In Section Q, page 89, 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 projects capital costs to be \$3,750 per station.
- The applicant states that capital costs consist of water treatment, patient TVs, and patient chairs.

In Section F, page 45, the applicant states that there are no start-up costs or initial operating costs for an existing facility.

**Availability of Funds**

In Section F, page 43, the applicant states that the capital cost will be funded, as shown in the table below.

**Sources of Capital Cost Financing**

Type	Renal Care Group of the South, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$7,500	\$7,500
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$7,500	\$7,500

\* OE = Owner's Equity

Exhibit F-2 contains a letter from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., parent company to Renal Care Group of the South, Inc., stating its commitment to fund the project through its cash reserves.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

**Financial Feasibility**

The applicant provided pro forma financial statements for the first 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 the second full fiscal year following completion of the project, as shown in the table below.

RCG Caswell	1 <sup>st</sup> FFY CY 2023	2 <sup>nd</sup> FFY CY 2024
Total Treatments	7,101	7,817
Total Gross Revenues (Charges)	\$44,672,674	\$49,176,793
Total Net Revenue	\$1,825,084	\$2,015,737
Average Net Revenue per Treatment	\$257.01	\$257.48
Total Operating Expenses (Costs)	\$1,901,001	\$1,990,839
Average Operating Expense per Treatment	\$267.70	\$254.68
Net Income	(\$75,917)	\$24,898

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

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- 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.

**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 for all the reasons described above.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
  - 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 revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to relocate no more than two dialysis stations pursuant to Policy ESRD-2 from BMA Burlington to RCG Caswell for a total of no more than 17 stations upon project completion.

On page 113, the 2021 SMFP defines the service area for dialysis stations as “*the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Caswell County. Facilities may also serve residents of counties not included in their service area.

**Caswell County Dialysis Facilities**

Facility Name	Certified Stations as of 12/31/2019	# of IC Patients as of 12/31/2019	Utilization by Percent as of 12/31/2019	Patients Per Station
Renal Care Group-Caswell	11	41	93.18%	3.72
<b>Total</b>	11	41	93.18%	3.72

Source: 2021 SMFP, Table 9A, page 120

In Section G, page 50, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Caswell County. The applicant states:

*“The 2021 SMFP, Table 9A indicates that RCG Caswell is the sole dialysis facility in Caswell County. The SMFP Table 9B indicates there is an eight station deficit in Caswell County. Relocating two stations to RCG Caswell obviously does not totally satisfy the deficit, but does help ensure additional capacity for the ESRD patients of*

*Caswell County. Relocating stations to a county that will continue to have a deficit of stations does not cause unnecessary duplication.”*

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:

- RCG Caswell is the only dialysis facility Caswell County.
- Caswell County has an eight-station deficit.
- 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 relocate no more than two dialysis stations pursuant to Policy ESRD-2 from BMA Burlington to RCG Caswell for a total of no more than 17 stations upon project completion.

In Section Q, page 99, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	As of 05/01/2021	2 <sup>nd</sup> Full Fiscal Year CY 2024
Administrator (FMC Clinic)	1.00	1.00
Registered Nurses (RNs)	2.00	2.00
Technicians (PCT)	3.00	4.00
Dietician	0.50	0.67
Social Worker	0.50	0.67
Maintenance	0.25	0.33
Administration/Business Office	0.50	0.50
Other (FMC Director of Operations)	0.125	0.15
Other (FMC Chief Technician)	0.125	0.15
Other (FMC In-Service)	0.125	0.15
<b>Total</b>	<b>8.13</b>	<b>9.62</b>

The assumptions and methodology used to project staffing are provided in Section Q, page 100. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.4. In Section H, page 52, 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:

- The facility offers competitive salaries and personnel benefits to maintains staffing levels.
- New employees are required to complete a 10-week training program that includes clinical training, corporate policy and procedures and safety precautions.

**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.



The applicant proposes to relocate no more than two dialysis stations pursuant to Policy ESRD-2 from BMA Burlington to RCG Caswell for a total of no more than 17 stations upon project completion.

### **Ancillary and Support Services**

In Section I, page 54, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 54-59, 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:

- RCG Caswell is an existing dialysis facility with ancillary and support services in place, such as human resources, staff training, dietary, housekeeping, and social services.
- In addition to ancillary and support services provided by the facility, Fresenius Medical Care, parent organization to Renal Care Group of the South, Inc., provides resources through their clinical initiatives department, technical services department and their regulatory affairs and law departments.

In Section I, page 59, the applicant describes its efforts to develop relationships with other local health care and social service providers.

- The applicant is an existing provider with established relationships with physicians, local hospitals, and other health professionals within the community.
- The applicant states that it has agreements in place for lab services, a hospital affiliation agreement and a transplant agreement.

In Section I, page 59, the applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on its working relationships with Dan River Access Center, and Vascular and Vein Specialists of Greensboro, where ESRD patients received dialysis access surgeries and care, and its agreements in place for lab services, a hospital affiliation agreement and a transplant agreement.

### **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. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as

medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 67, the applicant provides the historical payor mix during CY 2020 for the proposed services, as shown in the table below.

<b>RCG Caswell Historical Payor Mix</b>	
<b>Payor Category</b>	<b>Dialysis Services as Percent of Total</b>
Self-Pay	2.16%
Insurance*	5.96%
Medicare*	61.25%
Medicaid*	10.00%
Other (Misc. including VA and Medicare Advantage Plans)	20.63%
<b>Total</b>	<b>100.00%</b>

\*Including may managed care plans.

In Section L, page 68, the applicant provides the following comparison.

<b>RCG Caswell</b>	<b>Percentage of Total Patients Served by the Facility or Campus during the Last Full FY before submission of the application<sup>^</sup></b>	<b>Percentage of the Population of the Service Area<sup>*</sup></b>
Female	38.3%	51.0%
Male	61.7%	49.0%
Unknown		
64 and Younger	55.0%	86.4%
65 and Older	45.0%	13.6%
American Indian	0.0%	0.9%
Asian	0.0%	0.9%
Black or African-American	40.0%	17.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	45.0%	66.8%
Other Race	15.0%	14.3%
Declined / Unavailable		

<sup>^</sup>All patients (in-center, home hemodialysis, and peritoneal)

<sup>\*</sup>The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

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 documents 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 69, the applicant states:

*“The facility 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 69, the applicant states that during the 18 months immediately preceding the application deadline, 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 70, 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 table below.

<b>RCG Caswell Projected Payor Mix CY 2024</b>	
<b>Payor Category</b>	<b>Dialysis Services as Percent of Total</b>
Self-Pay	2.16%
Insurance*	5.96%
Medicare*	61.25%
Medicaid*	10.00%
Other (Misc. including VA and Medicare Advantage Plans)	20.63%
<b>Total</b>	<b>100.00%</b>

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.16% of total services will be provided to self-pay patients, 61.25% to Medicare patients and 10.00% to Medicaid patients.

On pages 70-71, 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 based on the following:

- Payor mix is based on recent facility performance.

- Payor mix is calculated based upon treatment volumes as opposed to percent of patient.

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 72, 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 relocate no more than two dialysis stations pursuant to Policy ESRD-2 from BMA Burlington to RCG Caswell for a total of no more than 17 stations upon project completion.

In Section M, page 73, the applicant describes the extent to which health professional training programs in the area 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:

- Students and program directors have the opportunity to receive information about ESRD and observe the operation of the facility while patients are receiving treatments.

- Exhibit M-1 contains a letter addressed to Piedmont Community College encouraging the school to include RCG Caswell in their clinical rotations for nursing students.

**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 relocate no more than two dialysis stations pursuant to Policy ESRD-2 from BMA Burlington to RCG Caswell for a total of no more than 17 stations upon project completion.

On page 113, the 2021 SMFP defines the service area for dialysis stations as “*the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Caswell County. Facilities may also serve residents of counties not included in their service area.

**Caswell County Dialysis Facilities**

Facility Name	Certified Stations as of 12/31/2019	# of IC Patients as of 12/31/2019	Utilization by Percent as of 12/31/2019	Patients Per Station
Renal Care Group-Caswell	11	41	93.18%	3.72
<b>Total</b>	11	41	93.18%	3.72

Source: 2021 SMFP, Table 9A, page 120

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 74, the applicant states:

*“The applicant does not project to serve dialysis patients currently being served by another provider.*

...

*There is but as single operational dialysis facility with in-center dialysis stations within Caswell County: RCG Caswell.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 75, the applicant states:

*“Approval of this application will allow the facility to continue serving patients who reside in the area. Consequently, these patient swill have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to patients of the area.”*

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

Regarding the impact of the proposal on quality, in Section N, page 75, the applicant states:

*“Quality of care is always in the forefront at Fresenius Medical Care related facilities...Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”*

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 75, the applicant states:

*“All Fresenius Medical Care related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina.”*

See also Section L and C 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 105, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 128 of this type of facility located in North Carolina.

In Section O, page 80, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents of immediate jeopardy have not occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 128 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

### C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

## **SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES**

### **10A NCAC 14C .2203 PERFORMANCE STANDARDS**

- (a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard is not applicable to this review.
- (b) *An applicant proposing to increase the number of dialysis stations in:*  
(1) *an existing dialysis facility; or*  
(2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*  
*shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.*
- C- In Section C, page 26 and Section Q, page 85, the applicant projects that RCG Caswell will serve 50 in-center patients on 17 stations, or a utilization rate of 2.96 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (b) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 24-25, and Section Q, page 87, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.