

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 10, 2016

Findings Date: May 10, 2016

Project Analyst: Julie Halatek

Team Leader: Fatimah Wilson

Project ID #: G-11145-16

Facility: Renal Care Group – Caswell

FID #: 960925

County: Caswell

Applicant: Renal Care Group of the South, Inc.

Project: Add one dialysis stations for a total of 11 stations upon project completion

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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.

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Renal Care Group of the South, Inc. d/b/a Renal Care Group – Caswell (RCG Caswell) proposes to add one dialysis station for a total of 11 certified dialysis stations upon project completion.

#### **Need Determination**

The 2016 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 the January 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of four dialysis stations in Caswell County; therefore, based on the county need methodology, there is no need for additional

stations in Caswell County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported for RCG Caswell in the January 2016 SDR is 3.4 patients per station, which is at least 3.2 patients per week. This utilization rate was calculated based on 34 in-center dialysis patients and 10 certified dialysis stations as of June 30, 2015 (34 patients / 10 stations = 3.4 patients per station).

<b>April 1 Review – January 2016 SDR</b>		
Required SDR Utilization		80.0%
Center Utilization Rate as of 6/30/15		85.0%
Certified Stations		10
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>10</b>
In-Center Patients as of 6/30/15 (January 2016 SDR) (SDR2)		34
In-Center Patients as of 12/31/14 (July 2015 SDR) (SDR1)		33
<b>Step</b>	<b>Description</b>	<b>Result</b>
	Difference (SDR2 - SDR1)	1
(i)	Multiply the difference by 2 for the projected net in-center change	2
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/14	0.0606
(ii)	Divide the result of Step (i) by 12	0.0051
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/15 until the end of calendar year 2015)	0.0303
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	35.0303
(v)	Divide the result of Step (iv) by 3.2 patients per station	10.9470
	and subtract the number of certified and pending stations to determine the number of stations needed*	1

\*Note: According to Step Two of the facility need methodology in the January 2016 SDR, "Rounding" to the nearest whole number is allowed only in Step 1(C) and Step 2(B)(v). In these instances, fractions of 0.5000 or greater shall be rounded to the next highest whole number.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is one. Step (C) of the facility need methodology states, "The facility may apply to expand to meet the need established ..., up to a maximum of ten stations." The applicant proposes to add one new station and, therefore, is consistent with the facility need determination for dialysis stations.

**Policies**

There is one policy in the 2016 SMFP which is applicable to this review. Policy GEN-3: Basic Principles on page 39 of the 2016 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

*"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina*

*State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

#### Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 12-13, Section O, pages 59-65, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote safety and quality.

#### Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), pages 14-15, Section L, pages 52-56, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote equitable access.

#### Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c) and (d), pages 14-16, and Section N, page 58. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access, and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

#### Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need methodology in the January 2016 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

- (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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

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Renal Care Group of the South, Inc. d/b/a Renal Care Group – Caswell (RCG Caswell) proposes to add one dialysis station for a total of 11 certified dialysis stations upon project completion.

**Population to be Served**

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Caswell County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 23, the applicant provides the historical patient origin for RCG Caswell patients as of December 31, 2015, which is summarized in the following table:

<b>RCG Caswell Dialysis Patients by County/State 12/31/2015</b>	
<b>County/State</b>	<b>Number of Patients</b>
Caswell	22
Alamance	2
Person	1
Rockingham	1
Virginia	11
<b>Total</b>	<b>37</b>

In Section C.1, page 13, the applicant provides the projected patient origin for RCG Caswell for in-center patients for the first two operating years (OY) following completion of the project, as shown below.

<b>RCG Caswell Dialysis Patients by County/State – OYs 1 &amp; 2</b>				
<b>County</b>	<b>OY1 – CY 2017</b>	<b>OY2 – CY 2018</b>	<b>Patients as % of Total</b>	
	<b>In-Center</b>	<b>In-Center</b>	<b>OY1</b>	<b>OY2</b>
Caswell	25.3	27	62.8%	64.4%
Alamance	2	2	5.0%	4.8%
Person	1	1	2.5%	2.4%
Rockingham	1	1	2.5%	2.4%
Virginia	11	11	27.3%	26.1%
<b>Total</b>	<b>40.3</b>	<b>42</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant provides the assumptions and methodology used to project patient origin on pages 19-21. The applicant adequately identifies the population to be served.

**Analysis of Need**

RCG Caswell proposes to add one dialysis stations for a total of 11 certified dialysis stations upon project completion. In Section C, pages 19-21, the applicant states the need for the proposed project is based on the following factors:

- The first two full OYs of the project are expected to be CY 2017 and CY 2018.
- On December 31, 2015, RCG Caswell was providing dialysis treatment for 37 in-center patients, including 22 patients who reside in Caswell County, two patients who reside in Alamance County, one patient who resides in Person County, one patient who resides in Rockingham County, and 11 patients that reside in Virginia.
- The applicant assumes the Caswell County ESRD patient population utilizing the facility will increase at the rate of 7.2 percent per year, the Five Year Average Annual Change Rate (AACR) for Caswell County as published in the January 2016 SDR. The applicant states that no growth was calculated for the patients residing outside of Caswell County.
- The applicant states that RCG Caswell has a need for the one additional station due to current utilization of the existing stations, the facility need methodology which shows the potential need for one additional station, and because the projected patient population at the end of the first operating year corresponds with a utilization rate of approximately 90 percent even with the additional station.

**Projected Utilization**

In Section C.1, pages 19-21, the applicant provides the assumptions and methodology it uses to determine the need for additional dialysis stations at the facility. The applicant’s assumptions and methodology are summarized below:

- The Caswell County patient population will grow at a rate of 7.2 percent (the Five Year AACR for Caswell County as published in the January 2016 SDR) through the end of the second year of operation.
- The applicant assumes no increase for residents of other counties who utilize the facility but assumes those patients will continue to dialyze at RCG Caswell and are added to the calculations when appropriate.
- The project is scheduled for completion on December 31, 2016. OY1 is CY 2017. OY2 is CY 2018.

In Section C.1, pages 19-21, the applicant provides the calculations used to arrive at the projected in-center patient census for OY1 and OY2 as summarized in the table below.

<b>RCG Caswell</b>	<b>In-Center Dialysis</b>
Starting point of calculations is Caswell County patients dialyzing at RCG Caswell on December 31, 2015.	22
Caswell County patient population is projected forward by one year to December 31, 2016. Projection is based on the AACR for Caswell County (7.2%).	$22 \times 1.072 = 23.6$
Caswell County patient population is projected forward by one year to December 31, 2017, using the Five Year AACR (7.2%).	$23.6 \times 1.072 = 25.3$
The 15 patients from other counties and states are added. This is the projected census on December 31, 2017 (OY1).	$25.3 + 15 = 40.3$
Caswell County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (7.2%).	$25.3 \times 1.072 = 27.1$
The 15 patients from other counties and states are added. This is the projected census on December 31, 2018 (OY2).	$27.1 + 15 = 42.1$

The applicant projects to serve 40.3 in-center patients on 11 stations, which is 3.66 patients per station ( $40.3 \text{ patients} / 11 \text{ stations} = 3.66$ ), by the end of OY1 and 42.1 in-center patients on 11 stations, which is 3.83 patients per station ( $42.1 \text{ patients} / 11 \text{ stations} = 3.83$ ), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). The January 2016 SDR indicates that RCG Caswell's utilization rate was 85 percent (3.4 patients per station) as of June 30, 2015. In this application, the applicant projects the Caswell County in-center patient census will increase annually by 7.2 percent, which is consistent with the Caswell County AACR published in the January 2016 SDR. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Home Hemodialysis and Peritoneal Dialysis

In Section C.1, page 19, the applicant states:

*“This facility does not include a home therapies program. The existing RCG Caswell facility does not have sufficient space to accommodate a home therapies program. RCG believes it is most cost effective to not add home therapies at this location.”*

### **Access**

In Section L.1, pages 52-53, the applicant states that RCG Caswell provides dialysis services to all residents in its service area without qualifications and serves patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability. The applicant also states that it makes every reasonable effort to accommodate those with special needs and helps uninsured and underinsured patients with applying for assistance so it can serve low-income persons, racial and ethnic minorities, women, handicapped persons, elderly persons, and other underserved persons. The applicant projects 93.3 percent of its patients will have some or all of their services paid for by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

### **Conclusion**

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for one additional station at RCG Caswell, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

- (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

In Section E.1, page 27, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that this alternative was dismissed due to the growth rate of the patient population at RCG Caswell.
- Apply for the One Station Expansion – The applicant states the one additional station will help meet the growing demand for services at RCG Caswell. The applicant further states that maintaining the status quo will result in higher utilization rates and could possibly restrict patient admissions.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **Renal Care Group of the South, Inc. d/b/a Renal Care Group Caswell shall materially comply with all representations made in the certificate of need application.**
  2. **Renal Care Group of the South, Inc. d/b/a Renal Care Group Caswell shall develop and operate no more than one additional dialysis station for a total of no more than 11 certified stations which shall include any isolation or home hemodialysis stations.**
  3. **Renal Care Group of the South, Inc. d/b/a Renal Care Group Caswell shall install plumbing and electrical wiring through the walls for no more than 11 dialysis stations which shall include any isolation stations.**
  4. **Renal Care Group of the South, Inc. d/b/a Renal Care Group Caswell shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section 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 add one dialysis station for a total of 11 certified dialysis stations upon project completion.

### **Capital and Working Capital Costs**

In the table in Section F.1, page 29, the applicant states that the projected capital cost is \$5,200, which includes \$750 for water treatment equipment and \$4,450 for other equipment.

RCG Caswell is an existing dialysis facility with an ongoing operation; therefore, in Sections F.10-12, page 32, the applicant does not project any working capital needs.

### **Availability of Funds**

In Section F.2, page 30, the applicant states that cash reserves/owner's equity is being used to finance the proposed project.

Exhibit F-1 contains a March 15, 2016 letter from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., the parent company of the applicant, stating that the company is submitting a certificate of need application to add one station to RCG Caswell. The letter states that Fresenius Medical Care Holdings, Inc. has committed cash reserves in the amount of \$5,200 for the project's capital expenditure.

In Section F.8(b), page 31, the applicant states:

*“The 2014 Consolidated Balance Sheet reflects more than \$341 million in cash, and total assets exceeding \$18 billion. It is obvious that FMC has the resources necessary for all projects. This application will not interfere with the financing of any other projects currently filed, or being filed by RCG. The amount shown in the financial statements is more than adequate to finance all CON projects proposed, and under development.”*

In Section F.7(a), page 31, the applicant refers to Exhibit F-2 for a copy of the most recent audited financial statements for Fresenius Medical Care Holdings, Inc. for years ended December 31, 2013 and 2014. As of December 31, 2014, Fresenius Medical Care Holdings, Inc. had \$195,280,000 in cash and cash equivalents, \$18,507,042,000 in total assets and \$8,428,400,000 in net equity (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the project.

### **Financial Feasibility**

The applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B) in Section R, page 74, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

<b>Projected Revenues and Operating Expenses</b>		
<b>RCG Caswell</b>	<b>Operating Year 1 CY 2017</b>	<b>Operating Year 2 CY 2018</b>
Gross Patient Revenue	\$23,050,640	\$24,231,088
Deductions from Gross Patient Revenue	(\$21,414,174)	(\$22,510,817)
Net Patient Revenue	\$1,636,466	\$1,720,271
Total Operating Expenses	\$1,515,482	\$1,572,702
<b>Net Income/Profit</b>	<b>\$120,984</b>	<b>\$147,569</b>

The applicant’s projections of treatments and revenues are reasonable based on the number of patients projected for the first two operating years. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

In Section H.1, page 38, the applicant provides projected staffing and salaries. Form A in Section R, page 71, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges.

**Conclusion**

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

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Renal Care Group of the South, Inc. d/b/a Renal Care Group – Caswell (RCG Caswell) proposes to add one dialysis station for a total of 11 certified dialysis stations upon project completion.

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Caswell County. Facilities may also serve residents of counties not included in their service area.

The applicant operates the only existing dialysis facility in Caswell County and there are no other approved facilities. As of June 30, 2015, RCG Caswell was serving 34

patients weekly on 10 stations, which is 3.4 patients per station per week or 85 percent of capacity (34 patients / 10 stations = 3.4; 3.4 / 4 = 0.85 or 85%). At the end of Operating Year One, the applicant projects that RCG Caswell will be serving 40.3 patients weekly on 11 stations, which is 3.66 in-center patients per station per week or 91.5 percent of capacity (40.3 patients / 11 stations = 3.66; 3.66 / 4 = 0.915 or 91.5%). This meets the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates the need to add one additional dialysis station based on the number of in-center patients it currently serves and proposes to serve. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Caswell County. Consequently, the application is conforming to this criterion.

- (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.

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In Section H.1, page 38, the applicant provides the following table to illustrate the projected staffing for RCG Caswell at the end of OY2.

<b>RCG Caswell – Proposed Facility Staffing</b>	
<b>Position</b>	<b>Projected # of FTEs</b>
Medical Director*	
RN	2.0
Technician	4.0
Clinical Manager	1.0
Administrator	0.15
Dietician	0.40
Social Worker	0.40
Chief Tech	0.10
Equipment Tech	0.50
In-Service	0.15
Clerical	1.0
<b>Total</b>	<b>9.7</b>

\*The Medical Director is a contract position and is not an employee of the facility.

The following table shows the applicant’s projected number of direct care staff FTEs at RCG Caswell for OY2, as shown on page 41 of the application.

<b>RCG Caswell – Projected Direct Care Staff Hours – OY2</b>					
<b>Direct Care Positions</b>	<b># FTEs* [a]</b>	<b>Hours / Year / FTE [b]</b>	<b>Total Annual FTE Hours [c] = [a] x [b]</b>	<b>Total Annual Hours of Operation ** [d]</b>	<b>FTE Hours / Hours of Operation [e] = [c] ÷ [d]</b>
RN	2.0	2,080	4,160	3,120	1.33
Technician (PCT)	4.0	2,080	8,320	3,120	2.67
<b>Total</b>	<b>6.0</b>	<b>2,080</b>	<b>12,480</b>	<b>3,120</b>	<b>4.00</b>

\* FTEs should match the direct care Total FTE Positions [a + c] listed in the Facility Staffing table in Section H, Question 1.

\*\* Total annual hours of operation from the Proposed Hours of Operation table in Section H, Question 6.

The applicant states that the Medical Director is not directly employed by the facility but provides services on a contractual basis. In Section I.3, page 43, the applicant identifies Dr. Michael R. Fredericks as the current Medical Director for the facility. Exhibit I-6 contains a copy of a letter from Dr. Fredericks supporting the proposed project.

In Section H.3, page 39, the applicant describes its experience and process for recruiting and retaining staff. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (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.

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In Section I, pages 42-44, the applicant discusses the providers of the necessary ancillary and support services for the proposed facility. The applicant discusses coordination with the existing health care system on pages 43-44. Exhibits I-1 through I-6 contain documents from Danville Home Dialysis, Spectra Lab, Danville Regional Medical Center, Duke University Medical Center, and Dr. Michael R. Fredericks, which demonstrate that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information found in Section I and referenced Exhibits is reasonable and supports a finding of conformity with this criterion.

- (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

- (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

(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

(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 handicapped persons, 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;

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In Section L.7, pages 55-56, the applicant reports that 93.3 percent of the patients who received treatments at RCG Caswell had some or all of their services paid for by Medicare or Medicaid in CY 2015. The historical payor mix for patients dialyzing at RCG Caswell are shown in the table below, taken from Section L.7, page 56.

<b>RCG Caswell Historical Payor Mix – CY 2015</b>	
<b>Payment Source</b>	<b>% Total Patients</b>
Private Pay	0.5%
Commercial Insurance	6.2%
Medicare	69.1%
Medicaid	9.2%
Other Medicare Commercial	15.0%
<b>Total</b>	<b>100.0%</b>

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant’s service area.

<b>Percent of Population</b>						
<b>County</b>	<b>% 65+</b>	<b>% Female</b>	<b>% Racial &amp; Ethnic Minority*</b>	<b>% Persons in Poverty**</b>	<b>% &lt; Age 65 with a Disability</b>	<b>% &lt; Age 65 without Health Insurance**</b>
Caswell	20%	49%	39%	20%	15%	17%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table, 2014 Estimate as of December 22, 2015.>

\*Excludes "White alone" who are "not Hispanic or Latino"

\*\*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The *Southeastern Kidney Council Network 6 Inc. Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2014</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
<b>Gender</b>		
Female	7,064	44.2%
Male	8,934	55.8%
<b>Race</b>		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

The applicant demonstrates that it currently provides adequate access to medically underserved populations. 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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L.3(d), page 54, the applicant states that it has no obligation to provide uncompensated care or community service under federal regulations. In Section L.6, page 55, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, 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.1(b), page 53, the applicant projects that 93.3 percent of the patients who will receive treatments at RCG Caswell in the second operating year (CY 2018) will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected OY2 payor mix for the facility.

<b>RCG Caswell Projected Payor Mix – OY2</b>	
<b>Payment Source</b>	<b>% Total Patients</b>
Private Pay	0.5%
Commercial Insurance	6.2%
Medicare	69.1%
Medicaid	9.2%
Other Medicare Commercial	15.0%
<b>Total</b>	<b>100.0%</b>

The applicant's projected OY2 payor mix for the facility is the same as the historical payor mix reported by the applicant in Section L.7, page 56. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at RCG Caswell. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 55, the applicant describes the range of means by which a person will have access to the dialysis services at RCG Caswell, including admissions from nephrologists with medical privileges at the facility or via referral from a different provider to a nephrologist with medical privileges. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, 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

In Section M.1, page 57, the applicant states that RCG Caswell has sent a letter to Piedmont Community College inviting the school to include the RCG Caswell facility in clinical rotations for nursing students. Exhibit M-1 contains the referenced letter, dated March 15, 2016, from the applicant to Piedmont Community College. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
  - (16) Repealed effective July 1, 1987.
  - (17) Repealed effective July 1, 1987.
  - (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

### C

Renal Care Group of the South, Inc. d/b/a Renal Care Group – Caswell (RCG Caswell) proposes to add one dialysis station for a total of 11 certified dialysis stations upon project completion.

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Caswell County. Facilities may also serve residents of counties not included in their service area.

The applicant operates the only existing dialysis facility in Caswell County and there are no other approved facilities. As of June 30, 2015, RCG Caswell was serving 34 patients weekly on 10 stations, which is 3.4 patients per station or 85 percent of capacity ( $34 \text{ patients} / 10 \text{ stations} = 3.4$ ;  $3.4 / 4 = 0.85$  or 85%). At the end of Operating Year One, the applicant projects that RCG Caswell will be serving 40.3 patients weekly on 11 stations, which is 3.66 in-center patients per station or 91.5 percent of capacity ( $40.3 \text{ patients} / 11 \text{ stations} = 3.66$ ;  $3.66 / 4 = 0.915$  or 91.5%). This meets the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

In Section N.1, page 58, the applicant discusses how the proposed project would have a positive impact on the cost-effectiveness, quality, and access to the proposed services. The applicant states:

*“RCG does not expect this proposal to have effect on the competitive climate in Caswell County. There is only one facility in the county: RCG Caswell. The projected patient population for the RCG Caswell Facility begins with patients currently served by RCG, and a growth of that patient population consistent with the Caswell County five year average annual change rate of 7.2% as published within the January 2016 SDR.*

*RCG facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients will be relying on government payors (Medicare/Medicaid/VA). The facility must capitalize upon every opportunity for efficiency.*

*RCG facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives by offering another convenient venue for dialysis care and treatment."*

See also Sections B, C, E, F, G, H, and L where the applicant discusses the impact of the project on cost-effectiveness, quality, and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality, and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1), (3), and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (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 Exhibit O-2, the applicant identifies two kidney disease treatment centers located in North Carolina, owned and operated by the applicant or its parent company, Fresenius Medical Care Holdings, Inc., that were cited in the past 18 months for

deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. In Section O.3, page 63, the applicant states both facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (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 application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below.

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

(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year 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- RCG Caswell is an existing facility.

(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section C.1, pages 19-21, the applicant documents the need for the project and demonstrates that it will serve a total of 40.3 in-center patients on 11

stations at the end of the first operating year, which is 3.66 patients per station per week or a utilization rate of 91.5 percent. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section C.1, pages 19-21, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.