

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 15, 2019

Findings Date: February 15, 2019

Project Analyst: Bernetta Thorne-Williams

Assistant Chief: Lisa Pittman

Project ID #: P-11581-18

Facility: RAI Care Centers-Goldsboro

FID #: 170236

County: Wayne

Applicant: RAI Care Centers of North Carolina II, LLC

Project: Add no more than three dialysis stations for a total of no more than 21 dialysis stations upon completion of this project, Project I.D. # P-11346-17 (relocate entire dialysis facility to a new location in Goldsboro) and Project I.D. # P-11477-18 (add two dialysis stations)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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

RAI Care Centers of North Carolina II, LLC d/b/a RAI Care Centers-Goldsboro (RAI Goldsboro) proposes to add three dialysis stations to the existing facility for a total of no more than 21 certified dialysis stations upon completion of this project, Project I.D. P-11346-17 (relocate entire dialysis facility to a new location in Goldsboro) and Project I.D. # P-11477-18 (add two dialysis stations).

**Need Determination**

The 2018 State Medical Facilities Plan (2018 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of two dialysis stations in Wayne County. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the July 2018 SDR, is at least 3.2 patients per station per week, or 80%. 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 RAI Goldsboro in the July 2018 SDR is 4.06 patients per station per week, or 101.56% ( $4.0625 / 4$  patients per station = 1.0156). This utilization rate was calculated based on 65 in-center dialysis patients and 16 certified dialysis stations ( $65 \text{ patients} / 16 \text{ stations} = 4.0625$  patients per station per week). Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table:

<b>OCTOBER 1 REVIEW-JULY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/17		101.6%
Certified Stations		16
Pending Stations		2
<b>Total Existing and Pending Stations</b>		<b>18</b>
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		65
In-Center Patients as of 6/30/17 (Jan 2018 SDR) (SDR1)		52
Step	Description	Result
	Difference (SDR2 - SDR1)	13
(i)	Multiply the difference by 2 for the projected net in-center change	26
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17	0.5000
(ii)	Divide the result of Step (i) by 12	0.0417
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	0.5000
(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	97.5000
(v)	Divide the result of Step (iv) by 3.2 patients per station	30.4688
	and subtract the number of certified and pending stations to determine the number of stations needed	12.4688

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed exceeds ten stations. 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 three new stations, therefore the application is consistent with the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2018 SMFP which is applicable to this review. *POLICY GEN-3: BASIC PRINCIPLES* on page 33 of the 2018 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, pages 9-10, Section K.1(g), page 47, Section N.1, page 57, Section O, page 59, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

### **Promote Equitable Access**

The applicant describes how it believes the proposed project would promote equitable access in Section B.4, pages 10-11, Section C.3, page 17, Section L, pages 51-53, Section N.1, page 57, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

### **Maximize Healthcare Value**

The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4, pages 11-12, Section C.1, pages 14-16, Section F, pages 45-30, Section K, pages 40-47, Section N.1, page 57, and referenced exhibits. The information provided by the applicant

is reasonable and adequately supports the determination that the applicant's proposal would 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**

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 reasons stated above.

- (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.

### C

According to the July 2018 SDR, RAI Goldsboro was certified for 16 stations as of December 31, 2017. On August 22, 2017, the applicant received a Certificate of Need (Project I.D. # P-11436-17) to relocate the entire 16-station dialysis facility to a new location in Goldsboro. Additionally, on August 28, 2018, the applicant was approved in Project I.D. # P-11477-18 to add two stations. In this application, the applicant proposes to add three dialysis stations to the facility for a total of no more than 21 certified dialysis stations at RAI Goldsboro following completion of this project, Project I.D. # P-11436-17 and Project I.D. # P-11477-18

### **Patient Origin**

On page 365, the 2018 SMFP defines the service area for dialysis stations 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 is Wayne County. Facilities may serve residents of counties not included in their service area.

In Section C.1, page 14 and C.8, page 20, the applicant provides the historical and the projected patient origin for in-center (IC), home hemodialysis (HHD), and peritoneal dialysis (PD) patients, as illustrated in the tables below.

County	DIALYSIS PATIENTS AS OF JUNE 30, 2018		
	IC	HHD	PD
Wayne	64.0	0.0	2.0
Johnston	1.0	0.0	0.0
Sampson	1.0	0.0	0.0
<b>Total</b>	<b>66.0</b>	<b>0.0</b>	<b>2.0</b>

County	Operating Year 1 CY2020			Operating Year 2 CY2021			Percent of Total	
	IC	HHD	PD	IC	HHD	PD	OY1	OY2
Wayne	70.7	0.0	5.49	73.9	0.0	6.81	97.4%	97.6%
Johnston	1.0	0.0	0.0	1.0	0.0	0.0	1.3%	1.2%
Sampson	1.0	0.0	0.0	1.0	0.0	0.0	1.3%	1.2%
<b>Total*</b>	<b>72.00</b>	<b>0.0</b>	<b>5.00</b>	<b>75.00</b>	<b>0.0</b>	<b>6.00</b>	<b>100.0%</b>	<b>100.0%</b>

\*The applicant rounded down the total number of patients

In Section C, pages 14-17, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C, pages 14-17, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section B.2, page 7, the applicant states the application is filed pursuant to the facility need methodology in the 2018 SMFP utilizing data from the July 2018 SDR.

On pages 14-17, the applicant states:

- The applicant begins the projections for the future patient population of RAI Goldsboro by using the ending in-center patient census of 64 Wayne County patients, as of June 30, 2018.

- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Wayne County which is 5.9%, as published in the July 2018 SDR, to project the Wayne County patient population forward.
- The applicant does not project an increase in the patient population for Johnson County nor Sampson County.
- Operating Year 1 (OY1) = Calendar Year (CY) 2020  
Operating Year 2 (OY2) = Calendar Year (CY) 2021

Projected Utilization

In Section C, page 15, the applicant provides the methodology used to project in-center patient utilization, as illustrated in the following table,

The applicant begins with the Wayne County in-center patients as of June 30, 2018.	64
The applicant projects the Wayne County patients forward 6 months to December 31, 2018 using one half of the 5-year AACR, which is 0.295%	$64 \times 1.0295 = 65.9$
Subtract one patient projected to change to home PD	$65.9 - 1 = 64.9$
The applicant projects the Wayne County patients forward one year to December 31, 2019 using the 5-year AACR, which is 5.95%	$64.9 \times 1.059 = 68.7$
Subtract one patient projected to change to home PD	$68.7 - 1 = 67.7$
The applicant projects the Wayne County patients forward one year to December 31, 2020 using the 5-year AACR, which is 5.95%	$67.7 \times 1.059 = 71.7$
Subtract one patient projected to change to home PD	$71.7 - 1 = 70.7$
The applicant adds the two in-center patients from other counties (1 patient from Johnston County and 1 patient from Sampson County). This is the projected ending census for <b>Operating Year 1</b> (12/31/2020)	$70.7 + 2 = 72.7$
The applicant projects the Wayne County patients forward one year to December 31, 2021 using the 5-year AACR, which is 5.95%	$70.7 \times 1.059 = 74.9$
Subtract one patient projected to change to home PD	$74.9 - 1 = 73.9$
The applicant adds the two in-center patients from other counties (1 patient from Johnston County and 1 patient from Sampson County). This is the projected ending census for <b>Operating Year 2</b> (12/31/2021)	$73.9 + 2 = 75.9$

The applicant projects to serve 72 in-center patients at the end of CY1 and 75 in-center patients at the end of CY2. Thus, the applicant projects that RAI Goldsboro will have a utilization rate of 85.71% or 3.42 patients per station per week ( $72 \text{ patients} / 21 \text{ stations} = 3.4285 / 4 = 0.8571$  or 85.71%) at the end of CY1. The projected utilization of 3.42 patients per station per week at the

end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported for the following reasons:

- the applicant begins with the existing in-center patients,
- the applicant grows the Wayne County in-center patients using the Wayne County 5-year AACR (5.9%) and holds the patient population from other counties constant, and
- the utilization rate by the end of OY1 exceeds the minimum standard of 3.2 patients per station per week.

#### Home Hemodialysis and Peritoneal Dialysis

The applicant does not currently provide home hemodialysis. On page 40, the applicant states home hemodialysis training and support will continue to be provided at FMC Vernon. On page 16, the applicant states RAI Goldsboro will project its peritoneal patient population in the same manner as its in-center patient population, increasing this population by applying the 5-year AACR for Wayne County (5.9%) each year. On page 16, the applicant provides a table which demonstrates the projected growth in its PD training and support program. At the end of OY1 the applicant projects to serve 5 PD patients and at the end of OY2 the applicant projects to serve 6 PD patients.

Projected utilization is reasonable and adequately supported for the following reasons:

- the applicant begins with the existing PD patients, all of whom are from Wayne County, and
- the applicant grows the PD patients by the Wayne County 5-year AACR (5.9%).

#### Access

In Section L.1(a), page 51, the applicant states that each of FMC's 114 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons regardless of their ability to pay. In Section L.1, page 52, the applicant provides the projected payor mix during OY2, as illustrated below.

**Projected Payor Mix OY2**

<b>Payment Source</b>	<b>Percent of Total Revenue</b>	<b>Percent of In-Center Revenue</b>	<b>Percent of HHD Revenue</b>	<b>Percent of PD Revenue</b>
Self Pay/ Indigent/ Charity	1.23%	0.0%	0.0%	0.00%
Medicare	70.37%	70.07%	0.0%	71.16%
Medicaid	3.70%	4.00%	0.0%	0.00%
Commercial Insurance	7.41%	6.54%	0.0%	16.80%
Medicare / Commercial	16.05%	16.19%	0.0%	12.04%
Misc. (VA)	2.47%	3.22%	0.0%	0.00%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>0.0%</b>	<b>100.00%</b>

As shown in the table above, OY2, the applicant projects 86.42% of total services will be provided to Medicare (includes Medicare and Medicare/Commercial) and 3.70% to Medicaid patients.

On pages 52-55, the applicant provides the assumptions and methodology used to project payor mix during OY2. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization at RAI Goldsboro.

**Conclusion**

The Agency reviewed the:

- Application,
- Exhibits to the application, and
- 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 identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

(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

RAI Goldsboro does not propose the reduction, elimination or relocation of a facility or service in the proposed application. Therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to add three dialysis stations for a total of no more than 21 certified dialysis stations at RAI Goldsboro upon completion of the proposed project, Project I.D. # P-11436-17, and Project I.D. # P-11477-18

In Section E.1, page 24, 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 maintaining the status quo is not an effective alternative because of the high utilization at RAI Goldsboro. The applicant states that failure to add additional capacity to the facility could result in higher utilization rate and potentially restrict patient admission. Therefore, this alternative was rejected.
- Apply for fewer stations - The applicant states application of the facility need methodology indicates a need for up to 10 stations. The applicant opted to apply for three stations. The applicant states that applying for less would not be an effective alternative. Therefore, this alternative was rejected.
- Apply for more stations - The applicant states the new relocated facility's physical space can only accommodate three additional stations. Therefore, this alternative was rejected.

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

- the facility is operating above 80% capacity,
- the facility need methodology indicates a need for greater than ten additional stations, and

- maintaining the status quo does not address the need for additional stations at the facility and would result in higher utilization and potentially restrict patient admissions.

### **Conclusion**

The Agency reviewed the:

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

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

- 1. RAI Care Centers of North Carolina II, LLC shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to the facility need determination in the July 2018 SDR, the applicant shall develop no more than three additional dialysis stations for a total of no more than 21 certified stations at RAI Care Centers-Goldsboro upon completion of this project, Project I.D. P-11346-17 (relocate entire dialysis facility to a new location in Goldsboro), and Project I.D. # P-11477-18 (add two dialysis stations) which shall include any home hemodialysis training or isolation stations.**
  - 3. RAI Care Centers of North Carolina II, LLC shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations, which shall include any isolation or home hemodialysis training stations.**
  - 4. RAI Care Centers of North Carolina II, LLC 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 add three dialysis stations to the existing facility for a total of no more than 21 certified dialysis stations upon completion of this project, Project I.D. P-11346-17

(relocate entire dialysis facility to a new location in Goldsboro), and Project I.D. # P-11477-18 (add two dialysis stations).

**Capital and Working Capital Costs**

In Section F.1, pages 27, the applicant projects the total capital cost of the project as shown in the table below.

Water Treatment Equipment	\$2,250
Equipment/Furniture	\$9,000
<b>Total</b>	<b>\$11,250</b>

In Section F, pages 30-31, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project as RAI Goldsboro is an existing facility.

**Availability of Funds**

In Section F.2, page 28, the applicant states that the capital cost will be funded as shown in the table below.

**Sources of Capital Cost Financing**

Type	Bio-Medical Applications of North Carolina, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$11,250	\$11,250
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$11,250</b>	<b>\$11,250</b>

\* OE = Owner's Equity

Exhibit F.1 contains a letter dated September 17, 2018, from the Senior Vice President & Treasurer of Fresenius Medical Holdings, Inc. (FMC), which states,

*“This is to inform you that Fresenius Medical Holdings, Inc., is the parent company of RAI Care Centers of North Carolina II, LLC and RAI Care Centers - Goldsboro.*

*As Senior Vice President, I am authorized and do hereby authorize ... and commit cash reserves for the capital cost of \$11,250 as may be needed for this project.”*

Exhibit F-7 contains a copy of the audited financial statements for FMCH for the year ending December 31, 2017. The report indicates that as of December 31, 2017, FMCH had \$569,818,000 in cash and cash equivalents, \$19.8 billion in total assets and \$10.5 billion in net

assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

### **Financial Feasibility**

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), 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>Operating Year 1 CY2020</b>	<b>Operating Year 2 CY2021</b>
Total Treatments	10,522	10,966
Total Gross Revenues (Charges)	\$44,322,632	\$47,277,740
Total Net Revenue	\$3,369,087	\$3,604,210
Average Net Revenue per Treatment	\$320.19	\$328.67
Total Operating Expenses (Costs)	\$2,981,447	\$3,108,820
Average Operating Expense per Treatment	\$283.35	\$283.50
Net Income	\$387,640	\$495,391

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

The applicant proposes to add three dialysis stations to the existing facility for a total of no more than 21 certified dialysis stations upon completion of this project, Project I.D. P-11346-17 (relocate entire dialysis facility to a new location in Goldsboro), and Project I.D. # P-11477-18 (add two dialysis stations).

On page 365, the 2018 SMFP defines the service area for dialysis stations 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 is Wayne County. Facilities may serve residents of counties not included in their service area.

According to the July 2018 SDR, there are currently four operational dialysis facilities in Wayne County, including one operated by the applicant, and three operated by DaVita, Inc. Also, DaVita has been approved to develop a new dialysis facility, Coastal Plains Dialysis, but that facility was not operational as of December 31, 2017. Rosewood Dialysis, Project I.D. # Project I.D. # P-11451-18, was issued a certificate of need effective date of June 30, 2018. The existing and approved dialysis facilities in Wayne County are listed in the table below.

<b>WAYNE COUNTY DIALYSIS FACILITIES</b>				
<b>Dialysis Facility (Owner)</b>	<b>Certified Stations 12/31/2017</b>	<b># In-center Patients 1231/2017</b>	<b>Percent Utilization 12/31/2017</b>	<b>Patients per Station 12/31/2017</b>
Coastal Plains Dialysis (DaVita)*	0	0	NA	NA
Goldsboro Dialysis (DaVita)	27	97	89.81%	3.5926
Goldsboro South Dialysis (DaVita)	22	71	80.68%	3.2273
Mt. Olive Dialysis (DaVita)	15	50	83.33%	3.3333
RAI Care Centers - Goldsboro	16	65	101.56%	4.0625
<b>Total / Average</b>	<b>80</b>	<b>283</b>	<b>88.43%</b>	<b>3.5375</b>

Source: July 2018 SDR, Table B.

\*According to the data collection form 12 stations were certified effective 1/1/2018

As illustrated in the table above, the existing facilities in Wayne County are well utilized with an average utilization of 3.5 patients per station per week  $[283/80=3.5375]$  or 88.43%  $[3.5375/4=0.8843]$ .

In Section G.2, page 35, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wayne County. The applicant states,

*“All of the facilities which were certified as of December 31, 2017, were operating at or above the 80% threshold. ... With such high reported utilization rates, the applicant believes that there is no duplication of healthcare services.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services because the applicant adequately demonstrates that the proposed addition of three dialysis stations at RAI Goldsboro is needed in addition to the existing or approved dialysis stations.

### **Conclusion**

The Agency reviewed the:

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

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

### C

In Section H.1, page 36, 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 YEAR 2
Registered Nurse	3.00	3.50
Home Training Nurse	0.25	0.50
LPN	1.00	1.00
Patient Care Technician	6.00	7.00
Dietitian	0.50	0.50
Social Worker	0.50	0.50
Clinical Manager	1.00	1.00
Director of Operations	0.20	0.20
In-Service	0.20	0.20
Clerical	1.00	1.00
Chief Technician	0.20	0.20
Equipment Technician	0.50	0.50
<b>Total</b>	<b>14.35</b>	<b>16.10</b>

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, pages 92-93, which is found in Section R. In Section H, page 37, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit I-5, the applicant provides a letter from the medical director indicating his interest in continuing to serve as the medical director of RAI Goldsboro. In Exhibit H, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

In Section I.1, page 40, the applicant provides a list of the necessary ancillary and support services, as illustrated below.

<b>Ancillary and Support Services</b>	
<b>Services</b>	<b>Provider</b>
In-center dialysis/maintenance	RAI Goldsboro
Self-care training (in-center)	RAI Goldsboro
Home training: Home hemodialysis Peritoneal dialysis Accessible follow-up program	FMC Vernon
Psychological counseling	Goldsboro Psychiatric
Isolation – hepatitis	RAI Goldsboro
Nutritional counseling	RAI Goldsboro
Social Work services	RAI Goldsboro
Acute dialysis in an acute care setting	Wayne Memorial Hospital
Emergency care	Wayne Memorial Hospital
Blood bank services	Wayne Memorial Hospital
Diagnostic and evaluation services	Wayne Memorial Hospital
X-ray services	Wayne Memorial Hospital
Laboratory services	Spectra Laboratories
Pediatric nephrology*	UNC Hospitals
Vascular surgery	Wayne Health Vascular and Vein Center and Triangle Vascular
Transplantation services	UNC Hospitals, Vidant Health
Vocational rehabilitation & counseling	Vocational Rehab of Wayne County
Transportation	Goldsboro Transit Authority

\*In previously submitted applications the applicant stated that pediatric nephrology services would be provided by UNC Hospitals. Exhibit I.5 contains a letter from Eastern Nephrology stating, “*Our practice has been pleased to serve the patients of this area. ... I am confident that we will meet the needs of the ESRD patient population choosing to dialyze at RAI Care Centers – Goldsboro dialysis facility.*”

In Section I.3, pages 41-42, and Section I.4, page 42, the applicant describes its existing and proposed relationships with other local health care and social services providers. The applicant provides supporting documentation in Exhibit I. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

**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.

- (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

In Section K.2, page 47, the applicant indicates that the project does not involve any new construction or renovation of 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 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;

C

In Section L.7, page 55, the applicant provides the historical payor mix during CY2017, as shown below.

<b>Payment Source</b>	<b>Percent of Total Revenue</b>
Self Pay/Indigent/Charity	-0.20%
Medicare	73.30%
Medicaid	3.55%
Commercial Insurance	8.93%
Medicare / Commercial	11.70%
Misc. (VA)	2.73%
<b>Total</b>	<b>100.00%</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.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Wayne	16%	51%	47%	21%	13%	15%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

\* Excludes "White alone, not Hispanic or Latino"

\*\* "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. 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., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina’s based on the Network’s recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26<sup>1</sup>) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

**Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the

<sup>1</sup> <https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

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 handicapped persons 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.3, page 54, the applicant states:

*“RAI-G facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. ... The applicant will treat all patients the same regardless of race or handicap status.”*

In Section L.6, page 55 the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

### **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.

- (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, page 52, the applicant provides the projected payor mix during OY2, as illustrated below.

**Projected Payor Mix OY2  
CY2021**

<b>Payment Source</b>	<b>Percent of Total Revenue</b>	<b>Percent of In-Center Revenue</b>	<b>Percent of HHD Revenue</b>	<b>Percent of PD Revenue</b>
Self Pay/ Indigent/ Charity	1.23%	0.0%	0.0%	0.00%
Medicare	70.37%	70.07%	0.0%	71.16%
Medicaid	3.70%	4.00%	0.0%	0.00%
Commercial Insurance	7.41%	6.54%	0.0%	16.80%
Medicare / Commercial	16.05%	16.19%	0.0%	12.04%
Misc. (VA)	2.47%	3.22%	0.0%	0.00%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>0.0%</b>	<b>100.00%</b>

As shown in the table above, OY2, the applicant projects 86.42% of total services will be provided to Medicare (includes Medicare and Medicare/Commercial) and 3.70% to Medicaid patients.

On pages 52-53, the applicant provides the assumptions and methodology used to project payor mix during OY2. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization at RAI Goldsboro.

**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.

- (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.

In Section L.4, page 54, 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

In Section M.1, page 56, 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.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

(15) Repealed effective July 1, 1987.

(16) Repealed effective July 1, 1987.

(17) Repealed effective July 1, 1987.

(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall

demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add three dialysis stations to the existing facility for a total of no more than 21 certified dialysis stations upon completion of this project, Project I.D. P-11346-17 (relocate entire dialysis facility to a new location in Goldsboro), and Project I.D. # P-11477-18 (add two dialysis stations).

On page 365, the 2018 SMFP defines the service area for dialysis stations 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 is Wayne County. Facilities may serve residents of counties not included in their service area.

According to the July 2018 SDR, there are currently four operational dialysis facilities in Wayne County, including one operated by the applicant, and three operated by DaVita, Inc. Also, DaVita has been approved to develop a new dialysis facility, Coastal Plains Dialysis, but that facility was not operational as of December 31, 2017. Rosewood Dialysis, Project I.D. # Project I.D. # P-11451-18, was issued a certificate of need effective date of June 30, 2018. The existing and approved dialysis facilities in Wayne County are listed in the table below.

<b>WAYNE COUNTY DIALYSIS FACILITIES</b>				
<b>Dialysis Facility (Owner)</b>	<b>Certified Stations 12/31/2017</b>	<b># In-center Patients 1231/2017</b>	<b>Percent Utilization 12/31/2017</b>	<b>Patients per Station 12/31/2017</b>
Coastal Plains Dialysis (DaVita)*	0	0	NA	NA
Goldsboro Dialysis (DaVita)	27	97	89.81%	3.5926
Goldsboro South Dialysis (DaVita)	22	71	80.68%	3.2273
Mt. Olive Dialysis (DaVita)	15	50	83.33%	3.3333
RAI Care Centers - Goldsboro	16	65	101.56%	4.0625
<b>Total / Average</b>	<b>80</b>	<b>283</b>	<b>88.43%</b>	<b>3.5375</b>

Source: July 2018 SDR, Table B.

\*According to the data collection form 12 stations were certified effective 1/1/2018

As illustrated in the table above, the existing facilities in Wayne County are well utilized with an average utilization of 3.5 patients per station per week  $[283/80=3.5375]$  or 88.43%  $[3.5375/4=0.8843]$ .

In Section N.1, page 57, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 57, the applicant states:

*“RAI-G does not expect this proposal to have effect on the competitive climate in Wayne County. RAI-G does not project to serve dialysis patients currently served by another provider. The projected patient population for the RAI Goldsboro facility begins with patients currently served by RAI-G at other RAI-G locations within the county, and a growth of that patient population consistent with the Wayne County five year average annual change rate of 5.9% as published within the July 2018 SDR.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

### **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 reasons stated above.

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

### C

In Section A.11, page 5, the applicant states that RAI Care Centers of North Carolina II, LLC, is a wholly owned subsidiary of FMC. FMC operates 114 facilities in North Carolina. In Exhibit A.4,



the applicant provides a list of its affiliates which includes Bio-Medical Applications of North Carolina, Inc.

In Section O, page 62, the applicant states that, during the 18 months immediately preceding the submittal of the application, immediate jeopardy incidents related to quality of care occurred in none of these facilities. In Exhibit O-2, the applicant provides a copy of the most recent survey for RAI Goldsboro. After reviewing and considering information provided by the applicant and considering the quality of care provided at all facilities, including those related or affiliated with the applicant, 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.

(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.

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

*.2203(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- RAI Goldsboro is an existing facility.

*.2203(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, pages 14-17, the applicant demonstrates that RAI Goldsboro will serve a total of 72 in-center patients at the end of OY1 for a utilization rate of 85.71% or 3.42 patients per station per week ( $72 \text{ patients} / 21 \text{ stations} = 3.42 / 4 = 0.8571$  or 85.71%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

*.2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

- C- In Section C.1, pages 14-17, 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.