

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 18, 2019

Findings Date: December 18, 2019

Project Analyst: Gregory F. Yakaboski

Team Leader: Fatimah Wilson

Project ID #: P-11790-19

Facility: New River Dialysis

FID #: 130178

County: Onslow

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than 10 dialysis stations for a total of no more than 27 stations upon completion of this project and Project ID# P-11710-19 (relocate 8 stations to Richlands Dialysis)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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.

C

Total Renal Care of North Carolina, LLC (the applicant) proposes to add 10 dialysis stations at New River Dialysis for a total of 27 stations upon completion of this project and Project ID# P-11710-19 (relocate 8 stations to Richlands Dialysis). New River Dialysis currently offers both a peritoneal dialysis (PD) and a home hemodialysis (HHD) program. The parent company of Total Renal Care of North Carolina, LLC is DaVita, Inc. (DaVita).

#### **Need Determination**

The 2019 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to

Table D, page 63, in the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of 11 stations in Onslow County, but because there are facilities with a reported utilization of less than 80%, there is no county need determination for new dialysis stations for Onslow 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 New River Dialysis in the July 2019 SDR is 3.84 patients per station per week. This utilization rate was calculated based on 96 in-center dialysis patients and 25 certified dialysis stations as of December 31, 2018 (96 patients /25 stations = 3.84 patients per station per week). Application of the facility need methodology indicates that 26 additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		96.0%
Certified Stations		25
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>25</b>
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		96
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR1)		71
Step	Description	Result
	Difference (SDR2 - SDR1)	25
(i)	Multiply the difference by 2 for the projected net in-center change	50
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.7042
(ii)	Divide the result of Step (i) by 12	0.0587
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/17 until 12/31/18)	0.7042
(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	163.6056
(v)	Divide the result of Step (iv) by 3.2 patients per station	51.1268
	and subtract the number of certified and pending stations to determine the number of stations needed	26.1268

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 26 stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2019 SDR. 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 10 new stations and, therefore, is consistent with the facility need determination for dialysis stations.

**Policies**

There is one policy in the 2019 SMFP which is applicable to this review: *Policy GEN-3: Basic Principles*, on page 31 of the 2019 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.”*

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 11-12, Section N, page 49, Section O, pages 51-52, and Exhibit B-3. 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, pages 12- 13, Section C, pages 22-23, Section L, pages 44-46, Exhibit L-4 and Section N, page 49. 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, page 13, Section F, pages 29-31, Section K, pages 41-42, Section N, page 49 and Section Q. 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. The application is consistent with Policy GEN-3.

## **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.

- (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

The applicant proposes to add 10 dialysis stations for a total of 27 stations at New River Dialysis upon completion of this project and Project ID# P-11710-19 (relocate 8 stations to Richlands Dialysis).

**Patient Origin**

On page 369, the 2019 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.” New River Dialysis is in Onslow County. Thus, the service area for this review is Onslow County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin for in-center (IC), HHD, and PD patients at New River Dialysis.

Last Full Operating Year (OY) CY2018						
	# of IC Patients	% of Total	# of HHD Patients	% of Total	# of PD Patients	% of Total
Onslow	89	92.70%	1	100.00%	17	89.47%
Duplin	3	3.10%	0	0.00%	0	0.00%
Alamance	1	1.00%	0	0.00%	0	0.00%
Jones	1	1.00%	0	0.00%	0	0.00%
Pender	1	1.00%	0	0.00%	0	0.00%
Warren	1	1.00%	0	0.00%	0	0.00%
Craven	0	0.00%	0	0.00%	1	5.26%
Lenoir	0	0.00%	0	0.00%	1	5.25%
Total	96	100.00%	1	100.00%	19	100.00%

Source: Table on page 17.

Note: Totals might not foot due to rounding.

Second Full OY CY2022						
	# of IC Patients	% of Total	# of HHD Patients	% of Total	# of PD Patients	% of Total
Onslow	109	95.60%	5	100.00%	21	91.30%
Duplin	1	0.90%	0	0.00%	0	0.00%
Alamance	1	0.90%	0	0.00%	0	0.00%
Jones	1	0.90%	0	0.00%	0	0.00%
Pender	1	0.90%	0	0.00%	0	0.00%
Warren	1	0.90%	0	0.00%	0	0.00%
Craven	0	0.00%	0	0.00%	1	4.35%
Lenoir	0	0.00%	0	0.00%	1	4.35%
Total	114*	100.00%	5	100.00%	23	100.00%

Source: Table on page 18.

Note: Totals might not foot due to rounding.

\*The table had a mathematical error and listed the total of IC patients as 115. The correct total of IC patients is 114.

In Section C, pages 18-21, 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 17-21, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section B.1, page 10, the applicant states the application is filed pursuant to the facility need methodology in the 2019 SMFP utilizing data from the July 2019 SDR.

In Section Q, the applicant describes the assumptions and methodology used to project utilization of the facility, summarized as follows:

- The July 2019 SDR shows that New River Dialysis operated at a utilization rate of 96.0 percent (3.84 patients per station per week) as of December 31, 2018 based on 96 in-center patients and 25 certified dialysis stations. The applicant states that 89 of the 96 patients were residents of Onslow County with 7 patients residing in other counties.
- The applicant begins the projections for the future patient population of New River Dialysis by using the ending in-center patient census of 89 patients from Onslow County, as of December 31, 2018.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Onslow County which is 9.1%, as published in the July 2019 SDR, to project the Onslow County patient population forward.
- The applicant subtracts the eight dialysis stations to be relocated to Richlands Dialysis pursuant to Project I.D. #P-11710-19.
- The applicant subtracts the 16 IC patients projected to transfer their care to Richlands Dialysis as of January 1, 2021 [14 Onslow County patients and 2 patients from outside of Onslow County].

- The applicant does not project an increase of the patients who dialyze at the facility and live in other counties but adds the patients in at the appropriate points of time.
- The applicant projects the first full operating year of the project will be January 1, 2021 – December 31, 2021 (CY2021) and the second full operating year will be January 1, 2022 – December 31, 2022 (CY2022).

The information is reasonable and adequately supported for the following reasons:

- According to the July 2019 SDR, as of December 31, 2018, New River Dialysis was operating at a rate of 3.84 patients per station per day, or 96 percent utilization.
- The applicant demonstrates eligibility to add dialysis stations to its facility via the facility need methodology. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.

*In-Center Projected Utilization*

In Section C, pages 17-20, and Section Q, the applicant provides its projected utilization methodology based on its stated assumptions as summarized in the following table.

New River Dialysis	In-Center Patients
As of December 31, 2018, there were 89 Onslow County IC patients	89
Project the Onslow County IC patients forward one year to December 31, 2019, using the Five-Year AACR for Onslow County which is 9.1%.	$89 \times 1.091 = 97.099$
Project the Onslow County IC patients forward one year to December 31, 2020, using the Five-Year AACR for Onslow County which is 9.1%.	$97.099 \times 1.091 = 105.935$
Add the 7 patients from outside Onslow County. This is the ending patient census as of December 31, 2020.	$105.935 + 7 = 112.935$
Subtract the 16 IC patients projected to transfer their care to Richlands Dialysis as of January 1, 2021. [14 Onslow County patient and 2 patients from outside Onslow County.]	$105 - 14 = 91$ Onslow County patients $7 - 2 = 5$ Non-Onslow County patients Total overall starting census of 96
Project the Onslow County IC patients forward one year to December 31, 2021, using the Five-Year AACR for Onslow County which is 9.1%.	$91.935 \times 1.091 = 100.301$
Add the 5 patients from outside Onslow County. This is the ending patient census as of December 31, 2021. <b>This is the IC patient census at the end of OY1.</b>	$100.301 + 5 = \mathbf{105.301}$
Project the Onslow County IC patients forward one year to December 31, 2022, using the Five-Year AACR for Onslow County which is 9.1%.	$100.301 \times 1.091 = 109.428$
Add the 5 patients from outside Onslow County. This is the ending patient census as of December 31, 2022. <b>This is the IC patient census at the end of OY2.</b>	$109.528 + 5 = \mathbf{114.528}$

The applicant states on page 14 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2021) and OY2 (CY2022) the facility is projected to serve 105 and 114 in-center patients, respectively.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.889 patients per station per week, or 97.22% ( $105 \text{ patients} / 27 \text{ stations} = 3.889 / 4 = 0.9722$  or 97.22%).
- OY2: 4.222 patients per station per week, or 105.6% ( $114 \text{ patients} / 27 \text{ stations} = 4.222 / 4 = 1.056$  or 105.6%).

The projected utilization of 3.889 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 IC utilization is reasonable and adequately supported for the following reasons:

- The applicant starts with the 89 existing Onslow County patients and accounts for the eight stations and 16 IC patients projected to transfer their care to the Richlands Dialysis facility.
- The Onslow County patients are projected to increase based on 9.1% per year which is the Five-Year AACR for Onslow County as reported in Table D of the July 2019 SDR.
- The applicant projects no growth for patients who utilize the facility and live in other counties.
- 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 Projected Utilization

The applicant currently provides HHD and PD. In Section C, page 20, the applicant states New River Dialysis will project its home hemodialysis and peritoneal patient population growth at a rate of one patient per year for each service component beginning on January 1, 2019. On pages 20-21, the applicant provides tables which demonstrate the projected growth in its HHD and PD training and support program. At the end of OY1, CY2021, the applicant projects to serve 4 HHD patients and 22 PD patients and at the end of OY2, CY2022, the applicant projects to serve 5 HHD patients and 23 PD patients.

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

- the applicant begins with the existing HHD and PD patients, and
- the applicant grows the HHD and PD patients by one patient per year for each service component.

#### Access

In Section C, page 22, the applicant states:

*“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.*

*We will make every reasonable effort to accommodate all patients, especially those with special needs such as the handicapped, patients attending school or patients who work. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need.*

*New River Dialysis will help uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly, and other under-served persons.”*

In Section L, page 46, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>Payor Category</b>	<b>IC Services as a Percent of Total</b>	<b>HHD as a Percent of Total</b>	<b>PD Services as Percent of Total</b>
Medicare	79.2%	100.0%	73.7%
Medicaid	5.2%	0.0%	5.3%
Insurance	8.3%	0.0%	21.1%
Other (VA)	7.3%	0.0%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Table on page 46 of the application.

The projected payor mix is reasonable and adequately supported.

### **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 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.

C

The applicant does not propose a reduction or elimination of a service, or the relocation of a facility or a service. Therefore, Criterion (3a) is not applicable to this review.

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

#### CA

The applicant proposes to add 10 dialysis stations for a total of 27 stations at New River Dialysis upon completion of this project and Project ID# P-11710-19 (relocate 8 stations to Richlands Dialysis).

In Section E, page 28, 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 this alternative would not have addressed the growth at the facility and thus was not the least costly or most effective alternative.
- Relocate stations from another DaVita facility- the applicant states that its other facility in Onslow County, Southeastern Dialysis Clinic-Jacksonville (SEDC-Jacksonville), is already operating at over 80% utilization and relocating stations from SEDC-Jacksonville would have negatively impacted current patients at SEDC-Jacksonville, therefore this alternative was not the least costly or most effective alternative

On page 28, the applicant states that its proposal is the most effective alternative because it ensures the facility will proactively address the issues of access and growth at the facility.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Total Renal Care of North Carolina, LLC shall materially comply with all representations made in the certificate of need application.**

2. **Pursuant to the facility need determination in the July 2019 SDR, Total Renal Care of North Carolina, LLC shall develop no more than 10 additional dialysis stations for a total of no more than 27 certified stations at New River Dialysis upon completion of this project and Project ID# P-11710-19 (relocate 8 stations to Richlands Dialysis), which shall include any home hemodialysis training or isolation stations.**
  3. **Total Renal Care of North Carolina, 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 10 dialysis stations for a total of 27 stations at New River Dialysis upon completion of this project and Project ID# P-11710-19 (relocate 8 stations to Richlands Dialysis).

**Capital and Working Capital Costs**

In Section F, pages 29 and 31, the applicant states that the proposed project does not involve any capital expenditures or working capital costs as New River Dialysis is an existing facility.

**Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Form F.2, 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>1<sup>st</sup> Full Fiscal Year CY2021</b>	<b>2<sup>nd</sup> Full Fiscal Year CY2022</b>
Total Treatments	18,599	20,252
Total Gross Revenues (Charges)	\$6,563,960	\$7,121,521
Total Net Revenue	\$6,254,843	\$6,784,940
Average Net Revenue per Treatment	\$336	\$335
Total Operating Expenses (Costs)	\$3,731,101	\$3,946,867
Average Operating Expense per Treatment	\$201	\$195
Net Income	\$2,523,741	\$2,838,072

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q 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 because 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 10 dialysis stations for a total of 27 stations at New River Dialysis upon completion of this project and Project ID# P-11710-19 (relocate 8 stations to Richlands Dialysis).

On page 369, the 2019 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.*” New River Dialysis is in Onslow County. Thus, the service area for this review is Onslow County. Facilities may also serve residents of counties not included in their service area.

According to Table B the July 2019 SDR, there are two existing and one approved dialysis facilities in Onslow County. Information on these dialysis facilities, from Table B of the July 2019 SDR, is provided below:

<b>Dialysis Facility</b>	<b># of Certified Stations</b>	<b>Percent Utilization</b>	<b>Patients Per Station</b>
New River Dialysis (DaVita)	25	96.00%	3.8400
Southeastern Dialysis Center – Jacksonville (DaVita)	33	81.06%	3.2424
Richlands Dialysis* (DaVita)	0	0.00%	0.0000

Source: Table B, July 2019 SDR, page 48.

\*Project ID# P-11710-19 – Certificate of Need effective August 27, 2019

In Section G, page 34, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Onslow. The applicant states:

*“Both of the DaVita facilities in Onslow County were operating at 80% or greater utilization as reported in the July 2019 SDR. ... While adding stations at this facility does increase the number of stations in Onslow County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”*

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

- There is a facility need determination in the 2019 SMFP for the proposed addition of 10 stations.
- The applicant adequately demonstrates that the 10 proposed dialysis stations are 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 Q, Form H Staffing, the applicant provides current and projected OY2 staffing for the proposed services in full-time equivalents (FTEs) as illustrated in the following table.

POSITION	Current FTE Positions	OY2 PROJECTED FTE POSITIONS
RN	4.0	4.0
Technician (Patient Care)	10.0	11.0
Administrator	1.0	1.0
Dietician	1.0	1.0
Social Worker	1.0	1.0
Home Training RN	0.5	1.0
Administrative/ Business Office	1.0	1.0
Bio-med Technician	0.5	0.5
<b>Total</b>	<b>19.0</b>	<b>20.5*</b>

Source: Sections Q, Form H of the application.

\*Note: In Form H the total FTE is listed as 21 however, the correct total is 20.5.

The assumptions and methodology used to project staffing are provided in Sections H and Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H.2 and H.3, pages 36 and 37, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 37, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. In Exhibits H-1 through H-4 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 all 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 38, the applicant provides a list of the necessary ancillary and support services, as illustrated below.

<b>New River Dialysis Ancillary and Support Services</b>	
<b>Services</b>	<b>Provider</b>
In-center dialysis/maintenance	To be available on premises
Self-care training (in-center)	To be available on premises
Home training: Home hemodialysis Peritoneal dialysis Accessible follow-up program	New River Dialysis
Psychological counseling	To be available on premises
Isolation – hepatitis	To be available on premises
Nutritional counseling	To be available on premises
Social Work services	To be available on premises
Acute dialysis in an acute care setting	Onslow Memorial Hospital
Emergency care	Onslow Memorial Hospital
Blood bank services	Onslow Memorial Hospital
Diagnostic and evaluation services	Onslow Memorial Hospital
X-ray services	Onslow Memorial Hospital
Laboratory services	DaVita Laboratories Services, Inc.
Pediatric nephrology	Onslow Memorial Hospital
Vascular surgery	Onslow Memorial Hospital
Transplantation services	Vidant Medical Center
Vocational rehabilitation & counseling	NC Division of Vocational Rehab Services
Transportation	Onslow United Transit System

In Section I.2, pages 38-39, and Exhibit I, 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

The applicant does not propose to construct any new space or renovate any 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, page 45, the applicant provides the historical payor mix during CY2018 for the proposed services, as shown in the table below.

Payor Category	IC Services as a Percent of Total	HHD as a Percent of Total	PD Services as Percent of Total
Medicare	79.2%	100.0%	73.7%
Medicaid	5.2%	0.0%	5.3%
Insurance	8.3%	0.0%	21.1%
Other (VA)	7.3%	0.0%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Table on page 45 of the application.

In Section L, page 44, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	44.1%	44.8%
Male	55.9%	55.2%
Unknown	0.0%	0.0%
64 and Younger	51.4%	90.2%
65 and Older	48.6%	9.2%
American Indian	1.8%	0.9%
Asian	0.0%	2.2%
Black or African-American	51.4%	15.9%
Native Hawaiian or Pacific Islander	0.9%	0.3%
White or Caucasian	41.4%	65.9%
Other Race	4.5%	4.5%
Declined / Unavailable	0.0%	0.0%

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's

existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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.2, page 45, the applicant states it has no obligation to provide uncompensated care, community service or access by minorities or handicapped persons.

In Section L, page 45, the applicant states that during the last five years no patient civil rights equal access complaints have been filed against the facility.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 46, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation (CY2022) following completion of the project, as shown in the table below.

Payor Category	IC Services as a Percent of Total	HHD as a Percent of Total	PD Services as Percent of Total
Medicare	79.2%	100.0%	73.7%
Medicaid	5.2%	0.0%	5.3%
Insurance	8.3%	0.0%	21.1%
Other (VA)	7.3%	0.0%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Table on page 46 of the application.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that that 79.2% of total IC patient services will be provided to Medicare patients and 5.2% to Medicaid patients.

On page 46, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- the applicant bases the projected payor mix on the facility's historical payor mix, and
- the applicant's proposed patient origin is based on historical patient origin of the facility.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L.5, page 46, 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, page 48, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

### **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 10 dialysis stations for a total of 27 stations at New River Dialysis upon completion of this project and Project ID# P-11710-19 (relocate 8 stations to Richlands Dialysis).

On page 369, the 2019 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.*” New River Dialysis is in Onslow County. Thus, the service area for this review is Onslow County. Facilities may also serve residents of counties not included in their service area.

According to Table B the July 2019 SDR, there are three (two existing and one approved) dialysis facilities in Onslow County. Information on these dialysis facilities, from Table B of the July 2019 SDR, is provided below:

Dialysis Facility	# of Certified Stations	Percent Utilization	Patients Per Station
New River Dialysis (DaVita)	25	96.00%	3.8400
Southeastern Dialysis Center – Jacksonville (DaVita)	33	81.06%	3.2424
Richlands Dialysis* (DaVita)	0	0.00%	0.0000

Source: Table B, July 2019 SDR, page 48.

\*Project ID# P-11710-19 – Certificate of Need effective August 27, 2019

In Section N, page 49, 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 49, the applicant states,

*“The expansion of New River Dialysis will have no effect on competition in Onslow County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita.*

*The expansion of New River Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”*

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 Q 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 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.

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

C

In Section Q, Form A Facilities, the applicant provides a list of the over 90 dialysis facilities in North Carolina owned and operated by DaVita.

In Section O.2, page 51, the applicant states that, during the 18 months immediately preceding the submittal of the application an incident of immediate jeopardy occurred in one of these facilities, Waynesville Dialysis Center. The applicant provides documentation regarding the deficiency and subsequent measures taken by that facility to ensure compliance with CMS Conditions for Coverage. In Section O, page 52 and in Exhibit O, the applicant states that the deficiency at Waynesville Dialysis Center has been corrected and that Waynesville Dialysis Center was back in compliance as of June 7, 2019. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

**10 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- The applicant is not proposing to establish a new ESRD 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, pages 17-20, and Section Q, the applicant demonstrates that New River Dialysis will serve a total of 105 in-center patients at the end of OY1 (CY 2021) for a utilization rate of 97.2% or 3.889 patients per station per week (105 patients / 27 stations = 3.889/ 4 = 0.972 or 97.2%). The discussion regarding projected utilization 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, pages 17-20, and Section Q, the applicant provides the assumptions and methodology used to project utilization of the facility.