

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 26, 2018

Findings Date: June 26, 2018

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: P-11493-18

Facility: New River Dialysis

FID #: 130178

County: Onslow

Applicant: Total Renal Care of North Carolina, LLC

Project: Add three dialysis stations for a total of 25 dialysis stations upon completion of this project, Project I.D. # P-11416-17 (add two stations) and Project I.D. # P-11325-17 (add two 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

Total Renal Care of North Carolina, LLC d/b/a New River Dialysis [**New River Dialysis**] proposes to add three dialysis stations to the existing facility for a total of 25 certified dialysis stations upon completion of this project, Project I.D. # P-11416-17 (add two stations) and Project I.D. # P-11325-17 (add two 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 January 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of one dialysis station in Onslow 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 most recent 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 New River Dialysis in the January 2018 SDR is 4.1111 patients per station per week, or 102.78% (4.1111 / 4 patients per station = 1.0278). This utilization rate was calculated based on 74 in-center dialysis patients and 18 certified dialysis stations (74 patients / 18 stations = 4.1111 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>APRIL 1 REVIEW-JANUARY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/17		102.78%
Certified Stations		18
Pending Stations		4
<b>Total Existing and Pending Stations</b>		<b>22</b>
In-Center Patients as of 6/30/17 (SDR2)		74
In-Center Patients as of 12/31/16 (SDR1)		68
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	6
	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/16	0.1765
(ii)	Divide the result of step (i) by 12	0.0147
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/17 until 12/31/17)	0.0882
(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	80.5294
(v)	Divide the result of step (iv) by 3.2 patients per station	25.1654
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>3</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is three 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 40, Section N.1, page 50, Section O, page 51, 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, page 10, Section C.3, pages 15-16, Section L, pages 44-48, Section N.1, page 50, 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, page 11, Section C.1, pages 13-15, Section F, pages 24-29, Section K, pages 39-43, Section N.1, page 50, 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 the January 2018 SDR, New River Dialysis was certified for 18 stations as of December 1, 2017. On May 24, 2017, the applicant was approved (Project I.D. P-11325-17) to add two dialysis stations to the facility for a total 20 stations. On February 9, 2018, the applicant was approved (Project I.D. P-11416-17) to add two dialysis stations to the facility for a total 22 stations. In this application, the applicant proposes to add three dialysis stations to the existing facility for a total of 25 certified dialysis stations at New River Dialysis following project completion. The applicant does not provide home hemodialysis (HHD) and is not proposing to do so in this application. The applicant does currently provide peritoneal dialysis (PD) training and support and will continue to do so as indicated in this application.

### **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 Onslow County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 19, the applicant provides the historical patient origin for New River Dialysis for in-center (IC) and peritoneal dialysis (PD) patients as of June 30, 2017 as follows:

County	In-Center Dialysis Patients	Peritoneal Dialysis Patients
Onslow	64	16
Duplin	3	2
Jones	1	1
Pender	3	1
Georgia	1	0
Tennessee	1	0
Other states	1	0
<b>Totals</b>	<b>74</b>	<b>20</b>

In Section C.1, page 13, the applicant provides the projected patient origin for New River Dialysis for in-center (IC), home hemodialysis (HHD) and peritoneal dialysis (PD) patients for the first two years of operation following completion of the project as follows:

County	Operating Year 1 CY2020			Operating Year 2 CY2021			Percent of Total	
	IC	HHD	PD	IC	HHD	PD	OY1	OY2
Onslow	71	0	20	73	0	21	86.7%	87.0%
Duplin	3	0	2	3	0	2	4.8%	4.6%
Jones	1	0	1	1	0	1	1.9%	1.9%
Pender	3	0	1	3	0	1	3.8%	3.7%
Georgia	1	0	0	1	0	0	1.0%	0.9%
Tennessee	1	0	0	1	0	0	1.0%	0.9%
Other States	1	0	0	1	0	0	1.0%	0.9%
<b>Total</b>	<b>81</b>	<b>0</b>	<b>24</b>	<b>83</b>	<b>0</b>	<b>25</b>	<b>100.0%</b>	<b>100.0%</b>

In Section C, pages 13-15, 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 13-14, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section B.2, pages 6-7, the

applicant states the application is filed pursuant to the facility need methodology in the 2018 SMFP utilizing data from the January 2018 SDR.

On pages 13-14, the applicant states:

- The applicant begins the projections for the future patient population of New River Dialysis by using the ending in-center patient census of 64 patients, as of June 30, 2017.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Onslow County which is 3.1% to project the Onslow County patient population forward.
- The applicant does not project an increase in the facility's patient population residing outside of Onslow County.
- Operating Year 1 (OY1) = Calendar Year (CY) 2020  
Operating Year 2 (OY2) = Calendar Year (CY) 2021

#### Projected Utilization

In Section C, page 14, the applicant provides the methodology used to project in-center patient utilization, as illustrated in the following table,

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Begin with Onslow County patients dialyzing at New River Dialysis as of June 30, 2017.	64
Project the Onslow County patient population forward six months to December 31, 2017 using the Five-Year Average Annual Change Rate for Onslow County of 3.1%	$64 \times 1.0185 [1.0155]$ $= 65.184 [64.992]^*$
Project the Onslow County population forward one year to December 31, 2018 using the Five-Year Average Annual Change Rate for Onslow County of 3.1%.	$65.184 [64.992] \times$ $1.031 = 67.2047$ [67.0068]
Project the Onslow County population forward one year to December 31, 2019 using the Five-Year Average Annual Change Rate for Onslow County of 3.1%.	$67.2047 [67.0068] \times$ $1.031 = 69.28805$ [69.084]
Project the Onslow County population forward one year to December 31, 2020 using the Five-Year Average Annual Change Rate for Onslow County of 3.1%.	$69.28805 [69.084] \times$ $1.031 = 71.43598$ [71.2256]
<b>OY1:</b> Add 10 patients from outside Onslow County. This is the projected census for OY 1.	$71.43598 [71.2256] +$ $10 = 81.43598$ [81.2256]
Project the Onslow County population forward one year to December 31, 2021 using the Five-Year Average Annual Change Rate for Onslow County of 3.1%.	$71.43598 [71.2256] \times$ $1.031 = 73.65049$ [73.4336]
<b>OY2:</b> Add 10 patients from outside Onslow County. This is the projected census for OY 2.	$73.65049 [73.4336] +$ $10 = 83.65049$ [83.4336]

\*The applicant incorrectly calculates half of the AACR as 1.0185 rather than 1.0155, which results in an error in subsequent calculations. However, the error is immaterial to the result. Corrected numbers are shown in brackets.

Thus, the applicant projects that New River Dialysis will serve a total of 81 in-center patients at the end of OY1 for a utilization rate of 81.0% or 3.24 patients per station per week (81 patients / 25 stations = 3.24 / 4 = 0.81 or 81%). The projected utilization of 3.24 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 of in-center patients is reasonable and adequately supported for the following reasons:

- The applicant begins its utilization projection with the existing patients of New River Dialysis,
- The applicant grows the Onslow County patient population by the January 2018 SDR Onslow County AACR and holds the patient population from outside Onslow County constant, and
- The resulting utilization rate at New River Dialysis by the end of the first year is above the minimum standard of 3.2 patients per station per week.

Home Therapy Programs

The applicant does not currently provide home hemodialysis (HHD). On page 15, the applicant provides the following table showing its projections of peritoneal dialysis (PD) patients through the first two operating years of the project.

<b>PD Patient Projections</b>	<b>Start Date</b>	<b># of Patients Start of Year</b>	<b># of Patients End of Year</b>	<b>Average # of Patients in Year</b>
Interim Period	7/1/2017	21	22	21.5
Current Year	1/1/2018	22	23	22.5
Interim Period	1/1/2019	23	24	23.5
Operating Year 1	1/1/2020	24	25	24.5
Operating Year 2*	1/1/2021	21 [25]	22 [26]	21.5 [25.5]

Source: Table on page 15 of the application.

\*The applicant's projections for Operating Year 2 appear to be a typographical error. The corrected projections, which are based on the applicant's stated methodology, are shown in brackets.

On page 15, the applicant describes its assumptions as follows:

*“New River Dialysis had 20 PD patients as of June 30, 2017 based on information included in Table C of the January 2018 SDR. ... The period of growth begins July 1, 2017 and is calculated forward to December 31, 2021. It is reasonable to assume that the New River Dialysis home-training program will grow at a rate of at least one patient per year during the period of growth.”*

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

- The applicant begins its utilization projection with the existing PD patients of New River Dialysis,
- The applicant grows the patient population by only one patient per year.

Access

In Section C.3, page 15, the applicant states the facility's services are available to all residents of the service area without regard to income, race, gender, handicap, age or ability to pay. In Section L.7, page 45, the applicant provides the projected (CY2020) payor mix for New River Dialysis, as shown below.

<b>Payment Source</b>	<b>Percent of Total Patients</b>
Medicare/Medicaid	26.2%
Medicare	25.3%
Medicaid	4.0%
Commercial Insurance	5.1%
Medicare / Commercial	33.3%
Misc. (VA)	6.1%
<b>Total</b>	<b>100.0%</b>

As shown in the table above, New River Dialysis projects that 88.8% of its patients will be Medicare or Medicaid recipients in CY2020. In Section L.1, page 48, the applicant provides historical (CY2017) payor mix which the applicant states is the basis for projected payor mix for New River Dialysis. The projected payor mix is reasonable and adequately supported.

### **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

New River Dialysis 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

New River Dialysis proposes to add three dialysis stations to the existing facility for a total of 25 certified dialysis stations upon completion of this project, Project I.D. # P-11416-17 (add two stations) and Project I.D. # P-11325-17 (add two stations).

In Section E.1, page 23, 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 due to growth in utilization of the facility. Therefore, this alternative was rejected.
- Relocation stations from another DaVita facility - The applicant rejected this alternative because relocating stations from Southeastern Dialysis Center-Jacksonville *“would negatively impact the patients presently served by this 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 facility is operating above 80% capacity.
- The applicant’s need projections and the facility need methodology indicate a need for additional stations at the facility.
- 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.
- Relocation of stations from other facilities in Onslow County would negatively impact patients at those facilities.

#### **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. Total Renal Care of North Carolina, LLC d/b/a New River Dialysis shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to the facility need determination in the January 2018 SDR, Total Renal Care of North Carolina, LLC d/b/a New River Dialysis shall develop no more than three additional dialysis stations for a total of no more than 25 certified stations at New River Dialysis upon completion of this project, Project I.D. # P-11325-17 (add two dialysis stations) and Project I.D. # P-11416-17 (add two dialysis stations), which shall include any home hemodialysis training or isolation stations.**
  - 3. Total Renal Care of North Carolina, LLC d/b/a New River Dialysis 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. Total Renal Care of North Carolina, LLC d/b/a New River Dialysis 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

New River Dialysis proposes to add three dialysis stations to the existing facility for a total of 25 certified dialysis stations upon completion of this project, Project I.D. # P-11416-17 (add two stations) and Project I.D. # P-11325-17 (add two stations).

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

In Section F.1, pages 24, the applicant projects the total capital cost of the project as shown in the table below.

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Dialysis Machines	\$96,460
Equipment/Furniture	\$42,534
<b>Total</b>	<b>\$138,994</b>

In Section R, the applicant provides the assumptions used to project the capital cost.

In Section F.10 and F.11, pages 26-27, the applicant projects that there will be no start-up or initial operating costs associated with the proposed project as New River Dialysis is an existing facility.

**Availability of Funds**

In Section F.2, page 25, the applicant states that the capital cost will be funded as shown in the table below.

**Sources of Capital Cost Financing**

Type	DaVita, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$138,994	\$138,994
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing **</b>	<b>\$138,994</b>	<b>\$138,994</b>

\* OE = Owner's Equity

In Section F.2, page 31, the applicant states it will finance the capital costs with the accumulated reserves of DaVita, Inc., which is the parent company for the applicant. Exhibit F contains a letter dated March 15, 2018 from the Chief Accounting Officer, authorizing and committing \$138,994 for the capital costs of the project.

Exhibit F also contains a copy of the Securities and Exchange Commission Form 10-K Annual Report for DaVita, Inc. for the year ending December 31, 2016. The report indicates that as of December 31, 2016, DaVita, Inc. had \$550 million in cash and cash equivalents, \$14.1 billion in total assets and \$4.9 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	15,339	15,783
Total Gross Revenues (Charges)	\$4,254,938	\$4,379,197
Total Net Revenue	\$4,076,524	\$4,195,669
Average Net Revenue per Treatment	\$265.76	\$265.83
Total Operating Expenses (Costs)	\$3,627,638	\$3,728,367
Average Operating Expense per Treatment	\$236.50	\$236.23
Net Income	\$448,886	\$467,301

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
- Information publicly available during the review and used by the Agency

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

- The applicant adequately demonstrates that the 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

New River Dialysis proposes to add three dialysis stations to the existing facility for a total of 25 certified dialysis stations upon completion of this project, Project I.D. # P-11416-17 (add two stations) and Project I.D. # P-11325-17 (add two 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 Onslow County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, there are currently two operational dialysis facilities in Onslow County, both of which are owned and operated by the applicant, as shown below.

<b>ONSLow COUNTY DIALYSIS FACILITIES</b>				
<b>Dialysis Facility (Owner)</b>	<b>Certified Stations 6/30/17</b>	<b># In-center Patients 6/30/2017</b>	<b>Percent Utilization 6/30/2017</b>	<b>Patients per Station</b>
Southeastern Dialysis Center-Jacksonville (DaVita)	30	100	83.33%	3.3333
New River Dialysis (DaVita)	18	74	102.78%	4.1111

Source: January 2018 SDR, Table B.

Of the two DaVita facilities, New River Dialysis operated with the highest utilization rate of 102.78%.

In Section G.2, page 30, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Onslow County. The applicant states,

*“While adding stations at this facility does increase the number of stations in Onslow County, it serves to meet the need 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 because the applicant adequately demonstrates that the proposed addition of three dialysis stations at New River Dialysis 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 31, the applicant provides current and projected staffing for the proposed services, as illustrated in the following table.

<b>POSITION</b>	<b>CURRENT # FTES</b>	<b>PROJECTED # FTES OY2</b>
Registered Nurse	3.00	4.00
Technician (PCT)	7.00	10.00
Administrator	1.00	1.00
Dietitian	1.00	1.00
Social Worker	1.00	1.00
Home Training RN	2.00	2.00
Admin. Assistant	1.00	1.00
Biomed Technician	1.00	1.00
<b>Total</b>	<b>17.00</b>	<b>21.00</b>

The assumptions and methodology used to project staffing are provided in Sections H and R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, pages 32-33, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit I, the applicant provides a letter from the medical director indicating his interest in continuing to serve as the medical director of New River Dialysis. 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
- 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.

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

C

In Section I.1, page 35, 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	New River Dialysis
Self-care training (in-center)	New River Dialysis
Home training: Home hemodialysis Peritoneal dialysis Accessible follow-up program	New River Dialysis New River Dialysis New River Dialysis
Psychological counseling	New River Dialysis
Isolation – hepatitis	New River Dialysis
Nutritional counseling	New River Dialysis
Social Work services	New River Dialysis
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 Laboratory Services
Pediatric nephrology	Onslow Memorial Hospital
Vascular surgery	Onslow Memorial Hospital
Transplantation services	Vidant Medical Center
Vocational rehabilitation & counseling	NC Division of Vocational Rehab
Transportation	Onslow United Transit System.

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
- 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.

- (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 40, 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 48, the applicant provides the historical (CY2017) payor mix for New River Dialysis, as shown below.

Payment Source	Percent of Total Patients
Medicare/Medicaid	26.2%
Medicare	25.3%
Medicaid	4.0%
Commercial Insurance	5.1%
Medicare / Commercial	33.3%
Misc. (VA)	6.1%
<b>Total</b>	<b>100.0%</b>

As shown in the table above, New River Dialysis reports that 88.8% of its patients were Medicare or Medicaid recipients in CY2017.

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**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Onslow	9%	16%	33%	15%	12%	10%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

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

\*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable... The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28<sup>1</sup>. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6). However, a direct comparison to the applicant’s current payor mix would be of little value because the population data by age, race, or gender does not include information on the

<sup>1</sup>[http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015\\_NW-6\\_Annual-Report\\_Final-11-29-2016.pdf](http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf)

number of elderly, minorities, women or handicapped persons utilizing health services.

### **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 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 47, the applicant states:

*“New River Dialysis has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993.”*

In Section L.6, page 47, 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
- 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.

- (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.3, page 45, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation (CY2021) following completion of the project, as shown in the table below.

<b>Payment Source</b>	<b>Percent of Total Patients</b>
Medicare/Medicaid	26.2%
Medicare	25.3%
Medicaid	4.0%
Commercial Insurance	5.1%
Medicare / Commercial	33.3%
Misc. (VA)	6.1%
<b>Total</b>	<b>100.0%</b>

As shown in the table above, during the second full fiscal year of operation, the applicant projects to provide 84.8% of its services to Medicare patients (includes Medicare, Medicare/Medicaid and Medicare/Commercial) and 4.0% to Medicaid patients.

On page 45, the applicant states the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project is based on the facility's historical (CY2017) experience. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization at New River Dialysis.

**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.

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

C

In Section L.4, page 47, 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
- 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.

- (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 49, 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.

**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 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

New River Dialysis proposes to add three dialysis stations to the existing facility for a total of 25 certified dialysis stations upon completion of this project, Project I.D. # P-11416-17 (add two stations) and Project I.D. # P-11325-17 (add two 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 Onslow County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, there are currently two operational dialysis facilities in Onslow County, both of which are owned and operated by the applicant, as shown below.

<b>ONSLOW COUNTY DIALYSIS FACILITIES</b>				
<b>Dialysis Facility (Owner)</b>	<b>Certified Stations 6/30/17</b>	<b># In-center Patients 6/30/2017</b>	<b>Percent Utilization 6/30/2017</b>	<b>Patients per Station</b>
Southeastern Dialysis Center- Jacksonville (DaVita)	30	100	83.33%	3.3333
New River Dialysis (DaVita)	18	74	102.78%	4.1111

Source: January 2018 SDR, Table B.

In Section N.1, page 50, 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 50, the applicant states:

*“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 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 B.4, pages 9-10, the applicant discusses the methods it uses to ensure and maintain quality. In Exhibit O, the applicant lists two dialysis facilities in the state owned by DaVita, Southeastern Dialysis Center – Wilmington and Goldsboro South Dialysis, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant provides documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage for Goldsboro South Dialysis in Exhibit O of the application. The applicant provided documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage for Southeastern Dialysis Center-Wilmington in response to a request by the Agency for additional information. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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- New River Dialysis 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 13-14, the applicant demonstrates that New River Dialysis will serve a total of 81 in-center patients at the end of OY1 for a utilization rate of 81.0% or 3.24 patients per station per week ( $81 \text{ patients} / 25 \text{ stations} = 3.24 / 4 = 0.81$  or 81.0%). 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 13-14, 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.