

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 9, 2018

Findings Date: February 9, 2018

Project Analyst: Jane Rhoe-Jones

Assistant Chief: Lisa Pittman

Project ID #: P-11416-17

Facility: New River Dialysis

FID #: 130178

County: Onslow

Applicant(s): Total Renal Care of North Carolina, LLC

Project: Add two dialysis stations for a total of 22 stations upon completion of this project and Project ID #P-11325-17 (add 2 stations)

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 (TRC) d/b/a New River Dialysis (“the applicant”) proposes to add two dialysis stations for a total of 22 stations at New River Dialysis upon completion of this project and Project ID #P-11325-17 (add 2 stations). The applicant also provides home hemodialysis (HHD) and peritoneal dialysis (PD) training and support at New River Dialysis. However, this application is submitted for in-center (IC) expansion only.

Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2017 Semiannual Dialysis Report (SDR) for end-stage renal disease facilities (ESRD), the county need methodology shows there is no projected deficit or surplus of dialysis stations

in Onslow County. Therefore, the July 2017 SDR does not indicate a need for additional stations in Onslow County based on the county need methodology, which states that the county deficit must be 10 or greater to establish a need for additional stations.

However, an 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 because the utilization rate reported for New River Dialysis in the July 2017 SDR is 3.8 patients per station, or 94.4% ($3.7778 / 4 \text{ patients per station} = .9444$). This utilization rate was calculated based on 68 in-center dialysis patients and 18 certified dialysis stations ($68 \text{ patients} / 18 \text{ stations} = 3.8 \text{ patients per station}$). The July 2017 SDR also indicates that 18 dialysis stations were certified as of June 9, 2017 and reported by the applicant on the June 30, 2017 *Data Collection Form* for ESRD facilities.

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table:

NEW RIVER DIALYSIS -OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/16		94.4%
Certified Stations		18
Pending Stations		2
Total Existing and Pending Stations		20
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		68
In-Center Patients as of 6/30/16 (Jan 2017 SDR) (SDR1)		63
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	5
	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.1587
(ii)	Divide the result of Step (i) by 12	0.0132
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.1587
(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	78.7937
(v)	Divide the result of Step (iv) by 3.2 patients per station	24.6230
	and subtract the number of certified and pending stations to determine the number of stations needed	4.6230
Pending Stations: INCLUDE all previously approved stations to be added to this facility, which includes any stations certified after the cutoff date. Do NOT subtract any stations to be transferred from this facility.		

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

Policies

There is one policy in the 2017 SMFP which is applicable to this review, Policy GEN-3: Basic Principles. Policy GEN-3, on page 33 of the 2017 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 9-10, Section N.1, page 53 and Section O, page 54, 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(b), page 10, Section C.3, page 16, Section L, pages 47-51, Section N.1, page 53, 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(c), page 11 and Section N, page 53. 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 information in the application, including any exhibits, is reasonable and adequately supported because the applicant relies on existing policies, historical data, and verifiable sources to provide future projections and demonstrate conformity with Policy GEN-3.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add two new dialysis stations at New River Dialysis, an existing facility located at 111 Yopp Road in Jacksonville. Upon completion of this project and Project ID #P-11325-17 (add 2 stations), New River Dialysis will be certified for 22 dialysis stations.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Onslow County. Facilities may also serve residents of counties not included in their service area.

Although the application proposes expansion only of in-center dialysis stations, in Section C.8, page 20, the applicant identifies the in-center (IC), home hemodialysis (HH) and peritoneal dialysis (PD) patient populations served at New River Dialysis as of December 31, 2016, and illustrated below in the table:

NEW RIVER DIALYSIS PATIENT ORIGIN As of December 31, 2016			
County	# In-Center Dialysis Patients	# HH Dialysis Patients	# PD Dialysis Patients
Onslow	54	1	16
Duplin	6	0	2
Jones	1	0	1
Pender	4	0	1
Georgia	1	0	0
Other States	2	0	0
Total	68	1	20

In Section C.1, page 13, the applicant provides the projected patient origin for New River Dialysis for all patients for the first two years of operation following completion of the project as follows:

NEW RIVER DIALYSIS PROJECTED IN-CENTER PATIENT ORIGIN by COUNTY								
County	OY1 CY2019			OY2 CY2020			County Patients as % of Total	
	IC	HH	PD	IC	HH	PD	OY1	OY2
Onslow	59	4	19	61	6	20	82.0%	82.9%
Duplin	6	0	2	6	0	2	8.0%	7.6%
Jones	1	0	1	1	0	1	2.0%	1.9%
Pender	4	0	1	4	0	1	5.0%	4.8%
Georgia	1	0	0	1	0	0	1.0%	1.0%
Other States	2	0	0	2	0	0	1.0%	1.9%
Total	73	4	23	75	6	24	100.0%	100.0%

The applicant provides the assumptions and methodology used to project IC patient origin on pages 13-14. The applicant provides the assumptions and methodology used to project HHH and PD on pages 14-15. The applicant adequately identifies the IC population to be served.

Analysis of Need

In Section B.2, page 7, the applicant states that the need for the proposed project is based on the facility need methodology in the 2017 SMFP utilizing data from the July 2017 SDR. It proposes to add two dialysis stations to New River Dialysis for a total of 22 stations at the facility upon completion of this project and Project ID #P-11325-17. In Section N.1, page 53, 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 other [sic] involved in the dialysis process to receive services.”

The applicant uses the following assumptions in Section C.1, pages 13-14 of the application:

- Based on information in the July 2017 SDR, as of December 31, 2016, the utilization rate for New River Dialysis was 94.4% or 3.8 patients per station per week. This utilization was based on 68 in-center patients dialyzing on 18 stations. Fifty-four of the 68 patients were residents of Onslow County, 14 were from outside Onslow County (Duplin, Jones, Pender counties and out of state).
- In Project ID #P-11325-17, TRC was approved to add two dialysis stations at New River Dialysis in May 2017, for a total of 20 stations. Those stations, at the date of this decision have not yet been certified.
- OY1 is CY 2019
- OY2 is CY 2020
- The applicant uses a growth rate of 3.1% for the New River Dialysis facility, which is Onslow County’s Five-Year Average Annual Change Rate (AACR) as published in Table B of the July 2017 SDR for the 85 Onslow County in-center patients. Thus, the applicant assumes a 3.1% growth rate for the facility through the second operating year (see chart of projected center growth rate on page 14 of the application). The applicant projects no growth for patients living outside of Onslow County.
- The applicant projects that after the growth period beginning January 1, 2017 and ending December 31, 2020, New River Dialysis will have 75 in-center patients, 61 of whom will be from Onslow County.

Projected Utilization

The applicant’s methodology from Section C.1, page 14, is illustrated in the following table.

NEW RIVER DIALYSIS IN-CENTER PATIENT PROJECTIONS					
	Start Date	# SA* (service area = Onslow County) Patients x Growth Rate	SA Year End Census + # out of SA existing patients	Total Year End Census	Year End Date
Beginning SA census	12/31/2016	54			
Current Year	1/1/2017	54 x 1.031	55.674 + 14	69.674	12/31/2017
Interim Period	1/1/2018	55.674 x 1.031	57.39989 + 14	71.39989	12/31/2018
OY1	1/1/2019	57.39989 x 1.031	59.17929 + 14	73.17929	12/31/2019
OY2	1/1/2020	59.17929 x 1.031	61.01385 + 14	75.01385	12/31/2020

The applicant projects to serve 73 in-center patients by the end of OY1 for a utilization rate of 83.0% or 3.3 patients per station per week ($73 / 22 = 3.32$; $3.32 / 4 = .8295$) and 75 in-center patients by the end of OY2 for a utilization rate of 85.2% or 3.4 patients per station per week ($75 / 22 = 3.41$; $3.41 / 4 = .8522$) for the 22-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C.2203(b). The July 2017 SDR indicates that New River Dialysis operated at a utilization rate of 94.4% (3.7 patients per station) as of December 31, 2016. Based on data reported in the July 2016 and July 2017 SDRs, from December 31, 2015 to December 31, 2016, the in-center census at New River Dialysis increased from 46 to 68 patients, which is an annual rate of growth of 47.83%. In this application, the applicant assumes a projected annual rate of growth of 3.1% for the in-center patient census at New River Dialysis, which equals the Onslow County Five Year Average Annual Change Rate of 3.1%. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section L.1(a), pages 47-48, the applicant states that New River Dialysis makes its services available to all persons without qualification, including low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. In Section L.7, page 51, the applicant reports that 89.5% of the in-center patients who received treatments at New River Dialysis had some or all their services paid for by Medicare or Medicaid in CY2016. In Section L.1(b), page 48, the applicant projects 89.5% of its in-center patients will also be Medicare or Medicaid recipients; no change from its current payor mix. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses historical data that is clearly cited and is reasonable to use to make the assumptions used by the applicant with regard to identifying the population to be served and with regard to demonstrating the need the population projected to be served has for the proposed services.
- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need the population projected to be served has for the proposed services.
- The applicant uses historical data to project future access to the services it provides for all residents, including underserved groups.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

TRC does not propose the reduction or elimination of a service in the proposed application, but rather the addition of two dialysis stations pursuant to the facility need methodology in the 2017 SMFP, 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

In Section E.1, page 24, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option would not support the growth rate at the facility.
2. Relocate Stations from Another DaVita Facility – The applicant rejected this alternative because both DaVita facilities in Onslow County are operating at above 80% capacity. Relocating stations from the other facility would negatively impact patients currently receiving care there.

3. Apply to Add Two Stations – the applicant states that the two-station expansion would help to meet the growing demand at New River Dialysis.

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

In summary, the applicant adequately demonstrates that the proposal is its most effective alternative to meet the identified need.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the application is conforming to this criterion and 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 2017 SDR, Total Renal Care of North Carolina, LLC shall develop no more than two additional dialysis stations for a total of no more than 22 certified stations at New River Dialysis upon completion of this project and Project ID #P-11325-17 (add two 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 two additional dialysis stations for a total of no more than 22 dialysis stations which shall include any isolation stations.**
 4. **Total Renal Care of North Carolina, LLC d/b/a New River Dialysis shall provide an updated letter of support and commitment from the medical director to replace the letter found in Exhibit I-3 that is dated February 15, 2017 (formerly submitted with Project ID# P-11325-17).**
 5. **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

The applicant proposes to add two new stations at New River Dialysis, an existing facility located at 111 Yopp Road in Jacksonville. Upon completion of this project and Project ID #P-11325-17 (add 2 stations) New River Dialysis will be certified for 22 stations.

Capital and Working Capital Costs

In Section F.1, page 25, the applicant projects \$34,458 in capital costs, including \$29,700 for dialysis machines and \$4,758 for other equipment and furniture. In Section F.10, pages 27-28, the applicant states that there are no projected start-up expenses or initial operating expenses because it is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 26, the applicant states it will finance the capital costs with accumulated reserves (owner's equity). Exhibit F-5 contains a letter dated September 12, 2017, from the Chief Accounting Officer, authorizing and committing \$34,458 and "*any other funds that are necessary*" in capital costs for the project.

Exhibit F-7 contains the Consolidated Financial Statements for DaVita, Inc. for the year ending December 31, 2016. These statements indicate that as of December 31, 2016, it had a consolidated total of \$913,187,000 in cash and cash equivalents, \$18,741,257,000 in total assets and \$5,822,999,000 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 below in the table.

NEW RIVER DIALYSIS		
	Operating Year 1	Operating Year 2
Total Treatments*	14,524	15,117
Total Gross Revenues (Charges)	\$3,982,943	\$4,188,082
Total Net Revenue	\$3,820,426	\$4,020,681
Total Operating Expenses (Costs)	\$3,350,997	\$3,483,605
Net Income	\$469,429	\$537,076

*Adjusted for missed treatments.

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 applicant adequately demonstrates sufficient funds for the capital and operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

The applicant proposes to add two stations to New River Dialysis for a total of 22 certified dialysis stations at New River Dialysis upon completion of this project and Project ID #P-11325-17 (add 2 stations).

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Onslow County. Facilities may also serve residents of counties not included in their service area.

The July 2017 SDR indicates there are two existing dialysis facilities in Onslow County, as follows:

ONSLow COUNTY DIALYSIS FACILITIES EXISTING & APPROVED/CERTIFIED STATIONS & UTILIZATION as of June 9, 2017						
Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
New River Dialysis	DaVita	68	Jacksonville	18	*NA	94.44%
SEDC-Jacksonville	DaVita	100	Jacksonville	30	**+1	100.00%

* Project ID #P-11325-17; CON issued 6/24/2017 (add 2 stations). **Project ID #P-11326-13 (add 1 station).

As illustrated above, both of the existing dialysis facilities are owned and operated by the applicant, and both facilities have a utilization rate of greater than 90.0%.

The applicant explains why it believes its proposal would not result in the duplication of existing or approved dialysis services in Section G of the application.

The applicant adequately demonstrates its proposal would not result in an unnecessary duplication of existing or approved dialysis services in Onslow County based on the following analysis:

- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need for the proposed services.
- The applicant provides adequate documentation that the proposed services will not result in the unnecessary duplication of existing or approved health service capabilities or facilities.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

In Section H.1, page 32, the applicant provides a table as illustrated below, with the current and proposed staff in full time equivalents (FTEs) for New River Dialysis. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart. The applicant proposes to add 2.0 new FTEs as a result of the proposed project, as shown below in the table. Upon project completion, the applicant projects 19 FTEs.

NEW RIVER DIALYSIS CURRENT AND PROJECTED STAFFING			
Position	Current FTEs	Additional FTEs	Total Proposed FTEs
Registered Nurse	3.0	0.0	3.0
Patient Care Technician (PCT)	7.0	2.0	9.0
Administrator	1.0	0.0	1.0
Dietitian	1.0	0.0	1.0
Social Worker	1.0	0.0	1.0
Home Training RN	2.0	0.0	2.0
Administrative Assistant	1.0	0.0	1.0
Biomedical Technician	1.0	0.0	1.0
Total	17.0	2.0	19.0

In Section H, page 35, the applicant provides the projected direct care staff hours for New River Dialysis in OY2. In Section H.2, page 33 and Section I.3, page 37, the applicant identifies Dr. KV George Thomas, as the Medical Director of the facility. In Exhibit I-3, the applicant provides a copy of a February 15, 2017 letter signed by Dr. Thomas of Southeastern

Nephrology Associates supporting the project to add dialysis stations and confirming his continued commitment to serve as Medical Director (see Criterion (4), Condition #4). In Section H.3, pages 33-34, the applicant states that vacant staff positions are filled by one or more of the following: the DaVita Teammate Recruiter, Teammate Referral Program and/or Student Internship Program.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate documentation of the availability of adequate health manpower including direct care staff and management personnel for the provision of the proposed dialysis services.
- The applicant provides appropriate and credible documentation of support from the current and continuing Medical Director of New River Dialysis.
- The applicant provides appropriate and credible documentation of the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

In Section I.1, page 36, the applicant lists the providers of the necessary ancillary and support services at the existing facility. The applicant discusses coordination with the existing health care system on pages 37-38. Exhibits I-1 and I-3 contain documents from the facility administrator at New River Dialysis, DaVita Laboratory Services, Inc., and local physicians, respectively, documenting availability of the necessary ancillary and support services. The facility administrator's letter of support lists the following agreements: Onslow Memorial Hospital provides acute, emergency, blood bank, diagnostic, X-ray, surgical, vascular and pediatric nephrology services; Vidant Medical Center provides transplantation services; NC Division of Vocational Rehabilitation Services provides vocational services and Onslow United Transit System, Inc. provides transportation.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant documents the availability of necessary ancillary and support services for the provision of the proposed dialysis services.
- The applicant documents ongoing coordination with the existing health care system.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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 the proposed application, the applicant proposes to add two stations to the existing facility. The applicant does not propose any new construction at New River Dialysis. 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.1, of the application, the applicant provides the information required in this criterion.

The following table illustrates the actual payor mix for New River Dialysis during CY2016.

NEW RIVER DIALYSIS CY 2016	
Payor Source	Percent of Total Patients
Medicare	24.4%
Medicaid	1.1%
Commercial Insurance	4.4%
Medicare / Commercial	37.8 %
Medicare / Medicaid	25.6%
VA	6.7%
Total	100.0%

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 27-28¹. 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 number of elderly, minorities, women or handicapped persons utilizing health services.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant's historical payor mix is adequate documentation of the extent to which medically underserved populations utilize the applicant's existing services.

The application is conforming to this criterion based on a review of:

- Information in the application, including any exhibits.
 - Information which was publicly available during the review and used by the Agency.
- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L.3(d) page 50, 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

¹http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

subsequent amendment in 1993. The facility has no obligation under the Hill Burton Act.”

In Section L.6, page 46, the applicant states, in reference to any facilities owned by DaVita in the state, that there have been no civil rights equal access complaints filed within the last five years.

The application is conforming to this criterion based on a review of the:

- Information in the application, including any exhibits.
 - Information which was publicly available during the review and used by the Agency.
- (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 of the application, the applicant provides the information required by this criterion. The following table illustrates the projected payor mix during the second full fiscal year.

NEW RIVER DIALYSIS PROJECTED PAYOR MIX PY2 (2020)	
Payor Source	Percent of Total Patients
Medicare	24.4%
Medicaid	1.1%
Commercial Insurance	4.4%
Medicare / Commercial	37.8 %
Medicare / Medicaid	25.6%
VA	6.7%
Total	100.0%

As illustrated above, the applicant does not project a change in its projected payor mix from that of its current payor mix.

The application is conforming to this criterion based on a review of the:

- Information in the application, including any exhibits.
 - Information which was publicly available during the review and used by the Agency.
- (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 50, the applicant states:

“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at New River Dialysis. Patients, families and friends can obtain access by contacting a nephrologist with privileges at the facility. Should a patient contact the facility either directly or indirectly, the patient will be referred to a qualified nephrologist for evaluation and subsequent admission if it were found to be medically necessary. Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies ...”

Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M.1, page 52, the applicant states that New River Dialysis offered the facility as a site for student nurse clinical rotations at Coastal Carolina Community College. Exhibit M-2 contains a copy of the applicant’s offer to Coastal Carolina Community College regarding clinical training for its student nurses at New River Dialysis.

The information provided in Section M.1 and Exhibit M-2 is reasonable and credible. Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

The applicant proposes to add two stations to New River Dialysis for a total of 22 certified dialysis stations at New River Dialysis upon completion of this project and Project ID #P-11325-17 (add 2 stations; projected certification in January 2018).

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Onslow County. Facilities may also serve residents of counties not included in their service area.

The July 2017 SDR indicates there are two existing dialysis facilities in Onslow County, as follows:

ONSLow COUNTY DIALYSIS FACILITIES EXISTING & APPROVED/CERTIFIED STATIONS & UTILIZATION as of June 9, 2017						
Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
New River Dialysis	DaVita	68	Jacksonville	18	*NA	94.44%
SEDC-Jacksonville	DaVita	100	Jacksonville	30	**+1	100.00%

* Project ID #P-11325-17; CON issued 6/24/2017 (add 2 stations). **Project ID #P-11326-13 (add 1 station).

As illustrated above, both of the existing dialysis facilities are owned and operated by the applicant, and both facilities have a utilization rate of greater than 90.0%.

In Section N, 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 cost-effectiveness, quality and access to the proposed services. In Section N, page 53, 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 ..., this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by Total Renal Care of North Carolina, LLC.

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 other involved in the dialysis process to receive services.”

Conclusion

The application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative.
- The applicant adequately demonstrates that it will continue to provide quality services.

- The applicant adequately demonstrates that it will continue to provide access to medically underserved populations.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

- (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 insure and maintain quality. In Exhibit O-3, the applicant provides a listing of two dialysis facilities that were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application. However, each facility is back in compliance as of the date of this decision, as below illustrated.

DVA QUALITY CARE			
Facility	Survey Date	Back in Compliance	
Southeastern Dialysis Center-Kenansville	3/22/2016	Yes	6/10/2016
Durham Dialysis	3/22/2016	Yes	5/31/2016

The applicant provides sufficient evidence that quality care has been provided in the past.

- (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.1, pages 13-14, the applicant demonstrates that New River Dialysis will serve a total of 73 in-center patients at the end of OY1 (CY 2019) for a utilization rate of 82.9% or 3.31 patients per station per week ($73 \text{ patients} / 22 \text{ stations} = 3.318 / 4 = 0.8295$). 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 in-center utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.