

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 31, 2018

Findings Date: January 31, 2018

Project Analyst: Tanya S. Rupp

Team Leader: Lisa Pittman

Project ID #: H-11411-17

Facility: Dialysis Care of Moore County

FID #: 944674

County: Moore

Applicant: Total Renal Care of North Carolina, LLC

Project: Add two dialysis stations for a total of 25 stations

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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 (TRC), d/b/a Dialysis Care of Moore County (DC Moore County) proposes to add two stations to the existing facility pursuant to the facility need determination, for a total of 25 stations upon project completion.

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), Table D, the county need methodology shows there is a surplus of seven dialysis stations in Moore County; thus the applicant cannot apply to add any additional stations based on the county need methodology. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the individual dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. TRC is eligible to apply for

additional stations in its existing facility based on the facility need methodology because the utilization rate reported for DC Moore County in the July 2017 SDR, Table B, is 3.3478 patients per station per week, or 83.7% (3.3478 / 4 patients per station = 0.8369 or 83.7%). This utilization rate was calculated based on 77 in-center dialysis patients and 23 certified dialysis stations (77 patients / 23 stations = 3.3478 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:

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/16		83.7%
Certified Stations		23
Pending Stations		0
Total Existing and Pending Stations		23
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		77
In-Center Patients as of 6/30/16 (Jan 2017 SDR) (SDR1)		69
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	8
	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.2319
(ii)	Divide the result of Step (i) by 12	0.0193
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.2319
(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	94.8551
(v)	Divide the result of Step (iv) by 3.2 patients per station	29.6422
	and subtract the number of certified and pending stations to determine the number of stations needed	6.6422

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at DC Moore County is seven 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* 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, page 42, Section N.1, page 51, Section O, page 52 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 I, pages 37 – 38, Section L, pages 45 - 48, Section N.1, 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 equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B, page 11, Section K 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 information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant’s use of the facility need methodology in accordance with the July 2017 SDR.
- The applicant’s use of 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

TRC proposes to add two in-center dialysis stations to the existing facility for a total of 25 stations upon project completion. DC Moore County offers both peritoneal dialysis (PD) and home hemo-dialysis (HH) training programs.

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 Moore County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 20, the applicant provides a table showing the historical patient origin for in-center (IC) patients, PD patients and HHD patients served by DC Moore County, as shown below:

DC Moore County Dialysis Patients as of 12/31/2016

County	IC Pts.	HHD Pts.	PD Pts.
Moore	64	5	10
Cumberland	0	2	3
Harnett	2	0	1
Hoke	0	0	6
Lee	1	1	2
Montgomery	1	2	1
Randolph	0	1	0
Richmond	5	2	3
Robeson	2	0	1
Scotland	0	0	3
Total	77	13	30

In Section C.1, page 13, the applicant provides the projected patient origin for DC Moore County for IC, HHD and PD patients for operating year one (OY 1) and operating year two (OY 2) following completion of the proposed project, as shown below:

County	Operating Year One			Operating Year Two			County Pts. as % of Total	
	IC	HHD	PD	IC	HHD	PD	OY 1	OY 2
Moore	67	7	13	68	8	14	69.6%	70.3%
Cumberland	0	2	3	0	2	3	4.0%	3.9%
Harnett	2	0	1	2	0	1	2.4%	2.3%
Hoke	0	0	6	0	0	6	4.8%	4.7%
Lee	1	1	2	1	1	2	3.2%	3.1%
Montgomery	1	2	1	1	2	1	3.2%	3.1%
Randolph	0	1	0	0	1	0	0.8%	0.8%
Richmond	5	2	3	5	2	3	8.0%	7.8%
Robeson	2	0	1	2	0	1	2.4%	2.3%
Other States	2	0	0	2	0	0	1.6%	1.6%
Total	80	16	33	81	17	34	100.0%	100.0%

Totals may not sum due to rounding

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

Analysis of Need

In Section B.1, page 7, the applicant states the application is filed pursuant to the facility need methodology in the 2017 SMFP, which shows a need for seven additional stations at DC Moore County. The applicant proposes to add two dialysis stations to the facility for a total of 25 stations upon project completion.

In Section C.1, pages 13 - 15, the applicant uses the following assumptions in its projections:

In-Center Patients

- The applicant states that DC Moore County had 77 in-center patients as of December 31, 2016, 64 of whom lived in Moore County and 13 of whom lived in the other counties listed on page 20.
- The applicant applies the Five Year Average Annual Change Rate (AACR) of 1.6% for Moore County found in Table D of the July 2017 SDR to the Moore County patient population to project growth in that population.
- The applicant does not project growth for patients residing outside of Moore County; rather, those patients are added in at the end of the growth calculations for Moore County residents.

- The applicant states Operating Year 1 is Calendar Year 2019, January 1 through December 31, 2019, and Operating Year 2 is Calendar Year 2020, January 1 through December 31, 2020.

Projected Utilization of In-Center Patients

The applicant’s methodology, applying the 1.6% AACR, is illustrated in the following table, from page 14:

Date	# Patients	Growth Rate	End Patients	+ Out of SA Patients	Total Year End Census
01/01/17	64	1.6%	65.024	13	78.024
01/01/18	65.024	1.6%	66.064	13	79.064
01/01/19	66.064	1.6%	67.121	13	80.121
01/01/20	67.121	1.6%	68.195	13	81.195

The applicant rounds down for each year, and thus projects to serve 80 in-center patients or 3.2 patients per station per week ($80 / 25 = 3.20$) by the end of Operating Year 1 and 81 in-center patients or 3.2 patients per station per week ($81 / 25 = 3.24$) by the end of Operating Year 2 for the facility. This satisfies 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). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth in in-center dialysis patients at DC Moore County.

Home Hemodialysis Patients

- The applicant states that DC Moore County had 13 HHD patients as of December 31, 2016, as shown in Table C of the July 2017 SDR.
- The applicant projects that the HHD patient population will increase by one patient per year.
- The applicant states Operating Year 1 is Calendar Year 2019, January 1 through December 31, 2019, and Operating Year 2 is Calendar Year 2020, January 1 through December 31, 2020.

Projected Utilization of HHD Patients

The applicant’s methodology is illustrated in the following table, from page 15:

Date	# Patients	Growth Rate	End Patients
01/01/17	13	+1	14
01/01/18	14	+1	15
01/01/19	15	+1	16
01/01/20	16	+1	17

Projected utilization of HHD patients is based on reasonable and adequately supported assumptions regarding continued growth at DC Moore County.

Peritoneal Dialysis Patients

- The applicant states that DC Moore County had 30 PD patients as of December 31, 2016, as shown in Table C of the July 2017 SDR.
- The applicant projects that the HHD patient population will increase by one patient per year.
- The applicant states Operating Year 1 is Calendar Year 2019, January 1 through December 31, 2019, and Operating Year 2 is Calendar Year 2020, January 1 through December 31, 2020.

Projected Utilization of PD Patients

The applicant's methodology is illustrated in the following table, from page 15:

Date	# Patients	Growth Rate	End Patients
01/01/17	30	+1	31
01/01/18	31	+1	32
01/01/19	32	+1	33
01/01/20	33	+1	34

Projected utilization of PD patients is based on reasonable and adequately supported assumptions regarding continued growth at DC Moore County.

Access

In Section L.1, pages 45 - 46, the applicant states that DC Moore County, by policy, will make dialysis services available to all residents in the service area, without qualification. The applicant states it will serve all patients without regard to race, color, national origin, gender, sexual orientation, age, religion or disability.

The applicant projects that 90.0% of its in-center patients will be Medicare or Medicaid recipients in CY 2020, based on its current facility patient data. 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 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

The applicant does not propose to reduce, eliminate or relocate a facility or a service. The applicant proposes to add two dialysis stations to an existing facility pursuant to the facility need determination.

- (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 – based on the growth rate at DC Moore County the applicant dismissed this option as not effective.
2. Relocate existing stations from another DaVita facility in Moore County - The applicant states that there are three existing DaVita facilities in Moore County. Two of those DaVita facilities are operating at over 80% capacity. One facility, Carthage Dialysis, is operating at 56.25% capacity, with 27 in-center patients and 12 stations.

However, the applicant states on page 24 that Carthage Dialysis is only open three days per week to meet the demands of the patients served by that facility. Therefore, the applicant states that relocating two stations from that facility would negatively impact the patients currently served. Indeed, if the facility is open for half of the number of shifts that a dialysis facility typically operates, then it is reasonable to conclude that the existing stations are utilized at over 100% of functional capacity [$27 / 12 = 2.25$; $2.25 / 2 = 1.125$ or 112.5%].

In Section E.2, page 24, the applicant states the facility need methodology demonstrates a need for the proposed stations at this facility, and continuing to operate at current capacity without adding additional stations could create a situation in which a third dialysis shift would be necessary or patients would have no choice of facilities. After considering these alternatives to its proposal, the applicant believes the most effective and least costly alternative is to add two stations to ensure adequate access for the patients of DC Moore County.

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.

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

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- The data cited is reasonable to use to support the assumptions of the applicant with regard to the least costly or most effective alternative for development of the proposed project.

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 and is approved subject to the following conditions.

- 1. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Moore County shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to the facility need determination in the July 2017 SDR, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Moore County shall develop no more than 2 additional dialysis stations for a total of no more than 25 certified stations at Dialysis Care of Moore County upon project completion, which shall include any home hemodialysis training or isolation stations.**

3. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Moore County shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to the 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

TRC proposes to add two dialysis stations to the existing facility for a total of 25 stations upon project completion.

Capital and Working Capital Costs

In Section F.1, page 25, the applicant states that it will not incur any capital costs to develop this project. In Sections F.10 - F.12, pages 27 - 28, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project.

Financial Feasibility

In Section R, the applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Forms B and C), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	CY 2019 OPERATING YEAR 1	CY 2020 OPERATING YEAR 2
Total Treatments	18,896	19,340
Total Gross Revenues (Charges)	\$5,803,165	\$5,943,229
Total Net Revenue	\$5,525,453	\$5,685,282
Total Operating Expenses (Costs)	\$4,256,674	\$4,353,398
Net Income	\$1,268,779	\$1,304,884

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

Conclusion

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

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- Historical data is used to provide future projections of costs and charges and demonstrate financial feasibility of the project.

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

TRC proposes to add two dialysis stations to the existing facility for a total of 25 stations upon project completion.

On page 373, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Moore County. Facilities may also serve residents of counties not included in their service area.

The applicant operates three dialysis facilities in Moore County, and is the only provider of dialysis services in the county, as shown below.

Facility	# Certified Stations	# Patients	# Patients per Station	% Utilization
Carthage Dialysis	12	27	2.25	56.25%
Dialysis Care of Moore County	23	77	3.35	83.70%
Southern Pines Dialysis Center	15	54	3.60	90.00%
Totals / Average	50	158	3.16	79.00%

As shown in the table above, based on the most recent SDR, two of the three DaVita dialysis facilities in Moore County are operating in excess of 80% utilization; in fact, Southern Pines Dialysis Center is operating at 90% utilization. It would appear, based on the numbers shown in the table, that Carthage Dialysis is underutilized. However, in Section E, page 24

and Section G.2, page 31, the applicant states the facility is only open three days per week, in order to better meet the needs of the patients and the scheduling requirements of the physicians at that facility. Thus, 56.25% utilization based on one-half the usual hours of operation is not an underutilized facility. Indeed, if the facility is open for half of the number of shifts that a dialysis facility typically operates, then it is reasonable to conclude that the existing stations are utilized at over 100% of functional capacity [$27 / 12 = 2.25$; $2.25 / 2 = 1.125$ or 112.5%]. In Section G.2, page 31, the applicant states that relocating dialysis stations from Carthage Dialysis would negatively impact the patients served at that facility.

In Section C, pages 13 - 15, the applicant demonstrates that DC Moore County will serve a total of 80 in-center patients at the end of OY 1 (CY 2019) for a utilization rate of 80.0% or 3.20 patients per station per week (80 patients / 25 stations = 3.20; $3.20 / 4 = .800$ or 80.0%), which satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b).

The applicant proposes to add two dialysis stations to DC Moore County pursuant to the facility need methodology. The applicant adequately demonstrates the need to add two additional station at DC Moore County based on the number of in-center patients it proposes to serve. The discussion on projected utilization found in Criterion (3) is incorporated herein by reference.

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

- The applicant uses established methodologies and 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 the current staffing for the facility, which includes 19.0 full-time equivalent (FTE) employees. The applicant projects to add one FTE

RN position and one FTE Patient Care Technician position as part of this project, for a total of 21.0 FTEs upon project completion. In Section H.3, pages 33 - 34, the applicant describes its experience and process for recruiting and retaining staff, and states it anticipates no difficulty with recruiting staff in the event it adds any staff. In Exhibit I-3, the applicant provides a copy of a letter from John Shepherd, M.D., expressing his commitment to continue to serve as the Medical Director for the facility.

In Section H.7, page 35, the applicant shows the existing and projected direct care staff at BMA Red Springs.

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 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 DC Moore County.
- 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 identifies the necessary ancillary and support services and indicates how they will be made available. The applicant discusses coordination with the existing health care system on pages 37 - 38. Exhibit I contains a copy of an agreement with DaVita Laboratory Services, Inc. Exhibit I-3 includes a letter from the medical director of the facility expressing his support for the proposed project. Exhibit I-3 also contains additional support letters from area physicians. Exhibit I-1 contains copies of agreements for home training, lab services, acute services and transplantation services.

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

- The applicant provides appropriate and credible documentation of the availability of necessary ancillary and support services for the provision of the proposed dialysis services.
- The applicant provides credible documentation of 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.

- (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, this Criterion is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose any new construction or renovation of existing space as part of this project.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
 - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 49, the applicant reports that 90.0% of the in-center patients and 87.2% of all patients who received treatments at DC Moore County had some or all of their services paid for by Medicare or Medicaid in CY 2016, as illustrated in the table below.

Historical Payor Mix CY 2016

Payment Source	IC Patients	HHD Patients	PD Patients	Percent of Total Patients
Medicare	31.4%	50.0%	24.4%	31.2%
Medicaid	0.0%	0.0%	4.9%	1.6%
Commercial Insurance	5.7%	7.2%	12.2%	8.0%
Medicare/Commercial	34.3%	21.4%	31.7%	32.0%
Medicare/Medicaid	24.3%	21.4%	24.2%	24.0%
VA	4.3%	0.0%	2.4%	3.2%
Total	100.0%	100.0%		100.0%

Totals may not sum due to rounding

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
Moore	24%	52%	23%	13%	9%	13%
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 ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². 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).

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

- The applicant’s historical payor mix is adequate documentation that it currently provides services to medically underserved populations.
- The applicant’s historical payor mix is adequate documentation of the extent to which medically underserved populations utilize the applicant’s existing services.

This determination is based on a review of the:

- Information in the application, including any exhibits.

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

²http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

- 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.

- (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 48, the applicant states, *“DC Moore County has no obligation under any federal regulations to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed on all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993. The facility has no obligation under the Hill Burton Act.”* In Section L.6, page 48, the applicant states, *“There have been no civil rights equal access complaints filed within the last five years.”*

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

- The applicant provides credible information about its lack of obligation to provide any uncompensated care or community service under any federal regulations.
- The applicant states it has not had any civil rights access complaints filed against it within the last five years.

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.

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

C

In Section L.1, page 45, the applicant states:

“DC Moore County, by policy, makes dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability.”

In Section L.1(b), page 47, the applicant projects that 90.0% in-center patients who will receive dialysis treatments at DC Moore County will have all or part of their services paid for by Medicare and or Medicaid, as illustrated below:

**DC Moore County
Projected Payor Mix OY 2 (CY 2020)**

Payment Source	IC Patients	HHD Patients	PD Patients	Percent of Total Patients
Medicare	31.4%	50.0%	24.4%	31.2%
Medicaid	0.0%	0.0%	4.9%	1.6%
Commercial Insurance	5.7%	7.2%	12.2%	8.0%
Medicare/Commercial	34.3%	21.4%	31.7%	32.0%
Medicare/Medicaid	24.3%	21.4%	24.2%	24.0%
VA	4.3%	0.0%	2.4%	3.2%
Total	100.0%	100.0%		100.0%

Totals may not sum due to rounding

The applicant states on page 46 that projected payor mix is based on its historical payor mix with no adjustments to the rates.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant’s projected payor mix adequately demonstrates that medically underserved populations will have adequate access to the proposed 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.

- (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 48, the applicant states:

“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at DC Moore County. ... Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies, found at Exhibit L-3. ...”

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant adequately demonstrates that the facility will provide a range of means by which a person can access the 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.

- (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 50, the applicant states that DC Moore County has been offered as a clinical training site for nursing students attending Richmond Community College. Exhibit M-2 contains a copy of the training agreement with Richmond Community College.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant adequately documents that the proposed health services will accommodate the clinical needs of health professional training programs in the area.

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.

- (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

TRC proposes to add two dialysis stations to the existing facility for a total of 25 stations upon project completion.

On page 373, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. The service area for this facility consists of Moore County. Facilities may also serve residents of counties not included in their service area.

There are only three existing dialysis facilities in Moore County, all of which are operated by DaVita, as shown below.

Facility	# Certified Stations	# Patients	# Patients per Station	% Utilization
Carthage Dialysis	12	27	2.25	56.25%
Dialysis Care of Moore County	23	77	3.35	83.70%
Southern Pines Dialysis Center	15	54	3.60	90.00%
Totals / Average	50	158	3.16	79.00%

As shown in the table above, based on the most recent SDR, two of the three DaVita dialysis facilities in Moore County are operating in excess of 80% utilization; in fact, Southern Pines Dialysis Center is operating at 90% utilization. It would appear, based on the numbers shown in the table, that Carthage Dialysis is underutilized. However, in Section E, page 24 and Section G.2, page 31, the applicant states the facility is only open three days per week, in order to better meet the needs of the patients and the scheduling requirements of the physicians at that facility. Thus, 56.25% utilization based on one-half the usual hours of operation is not an underutilized facility. Indeed, if the facility is open for half of the number of shifts that a dialysis facility typically operates, then it is reasonable to conclude that the existing stations are utilized at over 100% of functional capacity [$27 / 12 = 2.25$; $2.25 / 2 = 1.125$ or 112.5%]. In Section G.2, page 31, the applicant states that relocating dialysis stations from Carthage Dialysis would negatively impact the patients served at that facility.

In Section N, page 51 of the application, 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. The applicant states:

“The expansion of DC Moore County will have no effect on competition in Moore County. ... 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 DC Moore County 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 application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates the need for the proposal and that it is a cost-effective alternative.
- The applicant adequately demonstrates that it will provide quality services.
- The applicant adequately demonstrates that it will provide access to medically underserved groups.

This determination is based on a review of:

- the information in the application, including any exhibits

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

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

C

DaVita Inc. owns and operates over seventy facilities in North Carolina as of the date of this application. (See application page 5.) In Section O and referenced Exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period. In Section B-4, pages 9-10, the applicant discusses the methods it uses to ensure and maintain quality. In Section O, page 52 and Exhibit O-2, the applicant states that the most recent recertification survey for DC Moore County revealed that no condition-level deficiencies were cited.

In Exhibit O-3, the applicant states that out of the 70 facilities located in North Carolina operated by the applicant only the two listed below were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application.

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

In Section O, page 52 and Exhibit O-3, the applicant states that the most recent recertification survey for those two facilities revealed that each facility is currently in compliance with Medicare conditions of participation. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision.

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

- The applicant provides adequate and credible documentation of its current policies with regard to providing quality care.
- The applicant provides accurate information regarding past deficiencies and how those deficiencies were addressed.

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.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming to all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- The applicant is not proposing to establish a new End Stage Renal Disease facility

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

-C- In Section C, pages 13 - 15, the applicant demonstrates that DC Moore County will serve a total of 80 in-center patients at the end of OY 1 (CY 2019) for a utilization rate of 80.0% or 3.20 patients per station per week ($80 \text{ patients} / 25 \text{ stations} = 3.20$; $3.20 / 4 = .800$ or 80.0%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 13 - 15, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

- The applicant provides adequate and credible documentation that it meets the performance standard required by this Rule.
- The applicant provides all documentation of its assumptions and methodology required by this Rule.

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.