

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 8, 2018

Findings Date: June 8, 2018

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Project ID #: A-11492-18

Facility: Franklin Township Dialysis

FID #: 120162

County: Macon

Applicant: Total Renal Care of North Carolina, LLC d/b/a Franklin Township Dialysis

Project: Add no more than two dialysis stations for a total of no more than 11 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 d/b/a Franklin Township Dialysis (TRCNC), the applicant, currently operates a 9-station dialysis facility located at 80 Westgate Plaza, Franklin, Macon County. The applicant proposes to add two dialysis stations, pursuant to the facility need methodology, to the existing Franklin Township Dialysis (FTD) facility for a total of 11 certified dialysis stations upon project completion.

Need Determination

The 2018 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D in the January 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for Macon County.

However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for FTD in the January 2018 SDR is 4.11 patients per station. This utilization rate was calculated based on 37 in-center dialysis patients and 9 certified dialysis stations. (37 patients / 9 stations = 4.111 patients per station). The facility need methodology requires a facility’s utilization rate in the latest SDR to be at least 3.2 patients per station to be eligible to apply for additional stations based on facility need. Therefore, the applicant is eligible to apply for additional stations pursuant to the facility need methodology.

Application of the facility need methodology indicates that up to a maximum of ten additional stations are needed for this facility, as illustrated in the following table.

April 1 REVIEW-January 2018 SDR

Required SDR Utilization		80.00%
Center Utilization Rate as of 6/30/16		102.78%
Certified Stations		9
Pending Stations		0
Total Existing and Pending Stations		9
In-Center Patients as of 6/30/17 (SDR2)		37
In-Center Patients as of 12/31/16 (SDR1)		22
Step	Description	
	Difference (SDR2 - SDR1)	15
(i)	Multiply the difference by 2 for the projected net in-center change	30
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/16	1.3636
(ii)	Divide the result of Step (i) by 12	0.1136
(iii)	Multiply the result of Step (ii) by 6	0.6818
(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	62.2271
(v)	Divide the result of Step (iv) by 3.2 patients per station	19.4459
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	10

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is ten stations. The applicant proposes to add two

stations. Therefore, the facility need determination for dialysis stations is applicable to this review.

In summary, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2018 SMFP that is applicable to this review, Policy GEN-3: Basic Principles. Policy GEN-3: Basic Principles, page 33 of the 2018 SMFP, 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, referencing other application sections and exhibits with specific details. 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; and Section N.1, page 50. 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 in Section N.1, page 50. 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 FTD’s projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need. Therefore, the application is consistent with Policy GEN-3.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

C

TRCNC currently owns and operates FTD, a 9-station dialysis facility, in Macon County. The applicant proposes to add two dialysis stations, pursuant to the facility need methodology, to the existing facility for a total of 11 certified dialysis stations upon project completion.

The following table, summarized from page 4 of the application, illustrates the current and projected number of dialysis stations at FTD.

Stations	Description	Project ID #
9	Total existing certified stations as of the January 2018 SDR	
+2	Stations to be added at SKC as part of this project	A-11492-18
11	Total stations upon completion of proposed project	

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” FTD is located in Macon County; thus, the service area for this facility consists of Macon County. Facilities may also serve residents of counties not included in their service area.

FTD provides in-center (IC) dialysis services and peritoneal (PD) services. The applicant provides the current and projected patient origin at FTD on pages 19 and 13, respectively, as summarized in the following tables.

County	Current In-Center Patients As of 6/30/17		Current Peritoneal Patients As of 6/30/17	
	Patients	Percent	Patients	Percent
Macon	30	81.08%	5	45.45%
Buncombe	1	2.70%	0	0.00%
Cherokee	0	0.00%	2	18.18%
Clay	1	2.70%	3	27.27%
Georgia	0	0.00%	1	9.09%
Other States	5	13.51%	0	0.00%
Total	37	100.00%	11	100.00%

Totals may not sum due to rounding

County	First Full FY OY1 1/1/20-12/31/20		Second Full FY OY2 1/1/21-12/31/21		In-Center Patients as a Percent of Total	
	In-Center	Peritoneal	In-Center	Peritoneal	OY1	OY2
Macon	31	9	32	10	81.58%	82.05%
Buncombe	1	0	1	0	2.63%	2.56%
Cherokee	0	2	0	2	0.00%	0.00%
Clay	1	3	1	3	2.63%	2.56%
Georgia	0	1	0	1	0.00%	0.00%
Other States	5	0	5	0	13.16%	12.82%
Total	38	15	39	16	100.00%	100.00%

Totals may not sum due to rounding

In Section C, pages 13-15, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

The applicant proposes to add two dialysis stations to the existing FTD facility in Macon County for a total of 11 certified dialysis stations upon project completion. In Section C, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section C.1, page 13, the applicant states that the current utilization rate for FTD is 102.78%, per the January 2018 SDR, which provides patient data as of June 30, 2017.

In Section C.2, page 15, the applicant states:

“Section B-2 clearly outlines the need that the population to [be] served, the in-center patients of Franklin Township Dialysis, has for the two-station expansion proposed in the application.

This application does not call for any changes to home hemo or PD services at Franklin Township Dialysis.”

Section B.2, page 7, includes the ESRD facility need methodology table which shows a need for up to ten additional dialysis stations at FTD.

In Section N.1, page 50, the applicant discusses the need for the additional stations at FTD. The applicant states:

“..., 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 information is reasonable and adequately supported for the following reasons:

- the facility is currently operating at above 100% capacity,
- the applicant bases the future need for services upon the facility’s historical patient utilization, and
- the applicant utilizes the 5-year county average annual change rate (AACR) of 1.6% for Macon County patients only and does not grow the patient population from outside Macon County.

Projected Utilization for In-Center Patients

In Section C.1, pages 13-14, the applicant provides the calculations used to arrive at the projected in-center patient census for the first two years of operation following the completion of the project. The following table summarizes the applicant’s projection of in-center dialysis patients at FTD.

Begin June 30, 2017 with 30 Macon County patients	30
Project Macon County patient growth forward at 1.6% for six months to December 31, 2017	$30 \times 1.008 = 30.24$
Project Macon County patient growth forward at 1.6% for one year to December 31, 2018	$30.24 \times 1.016 = 30.72384$
Project Macon County patient growth forward at 1.6% for one year to December 31, 2019	$30.72384 \times 1.016 = 31.21542$
Project Macon County patient growth forward at 1.6% for one year to reach OY1 Census	$31.21542 \times 1.016 = 31.71487$
Add the 7 patients from outside Macon County. This is the projected ending census for OY1 (December 31, 2020).	$31.71487 + 7 = 38.71487$
Project Macon County patient growth forward at 1.6% for one year to reach OY2 Census	$31.71487 \times 1.016 = 32.2223$
Add the 7 patients from outside Macon County. This is the projected ending census for OY2 (December 31, 2021).	$32.2223 + 7 = 39.2223$

The applicant states that projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1, the facility is projected to serve 38 in-center patients and at the end of OY2, the facility is projected to serve 39 in-center patients.

- OY1: 38 in-center patients = 3.45 patients per station per week, a utilization rate of 86.4% (38 patients / 11 stations = 3.45 / 4 = 0.8636 or 86.4%).
- OY2: 39 in-center patients = 3.55 patients per station per week, a utilization rate of 88.6% (39 patients / 11 stations = 3.55/4 = 0.886 or 88.6%).

The projected utilization of 3.45 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

In Sections C.1 and C.7, pages 13-14 and 17-18, respectively, the applicants provide the methodology and assumptions used to project utilization at FTD. The project is based upon the facility need methodology. Based on the facility need methodology, FTD is eligible to add as many as ten stations. The applicant proposes to add two stations.

The applicant's methodology and assumptions are summarized below:

- FTD has an in-center patient census of 37 as of June 30, 2017, with 30 patients from Macon County,
- OY1 begins January 1, 2020 and ends December 31, 2020,
- OY2 begins January 1, 2021 and ends December 31, 2021,
- the January 2018 SDR 5-year AACR (1.6%) is applied to the Macon County patient population, and
- utilization for the 7 patients from outside Macon County is held constant.

Projected utilization for in-center patients is reasonable and adequately supported for the following reasons:

- the applicant bases the future utilization of services upon the facility's historical patient utilization, and
- the applicant grows only the Macon County patient population by the 5-year Macon County average annual change rate (AACR) of 1.6% .

Projected Utilization for Peritoneal Patients

In Section C.1, pages 14-15, the applicant provides the methodology used to arrive at the projected peritoneal patient census for the first two years of operation following the completion of the project. The applicant projects an increase of one patient per year during the growth period, beginning with 11 PD patients as of June 30, 2017, per the January 2018 SDR and reaching 15 patients at the end of OY1.

Access

In Section C.3, page 15, the applicant states:

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

Exhibit L-3(a) contains the facility’s financial policies. The applicant projects payor mix for the second operating year following completion of the project in Section L.1(b), page 45, by percent, as summarized below:

**Projected Payor Mix
OY2**

Payor Source	Total Patients	In-center Patients	PD Patients
Private Pay	0.0%	0.0%	0.0%
Medicare	15.0%	16.7%	10.0%
Medicaid	0.0%	0.0%	0.0%
Commercial Insurance	7.5%	3.3%	20.0%
Medicare / Commercial	42.5%	50.0%	20.0%
Medicare / Medicaid	30.0%	26.7%	40.0%
VA	5.0%	3.3%	10.0%
Other	0.0%	0.0%	0.0%
Total	100.0%	100.0%	100.0%

In Section L.1(b), page 45, the applicant states that the projected payor mix is based upon the facility’s payor mix during the last full operating year. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.

- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

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

NA

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

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

CA

TRCNC currently owns and operates FTD, a 9-station dialysis facility, in Macon County. The applicant proposes to add two dialysis stations, pursuant to the facility need methodology, to the existing facility for a total of 11 certified dialysis stations upon project completion.

In Section E, page 23, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain Status Quo – the applicant states that this alternative is not effective based on the growth rate at the facility.
- Apply for the Two-Station Expansion Facility Need Methodology – the applicant states that applying for the stations based on the facility need methodology helps to meet the demand for services at FTD.

On page 23, the applicant states that the project as proposed is the most effective alternative because it ensures that the facility will proactively address the issues of growth and access at the facility. The applicant states:

“As calculated in Section B-2, there is a need for additional stations. Continuing to operate at the current capacity could create a situation where the patients projected in Section C would have a third shift as their only option of dialyzing at Franklin Township Dialysis or even no option at all to choose Franklin Township Dialysis if

the patient population maxed out the facility's capacity because of maintaining the status quo."

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

- the facility is operating at above 100% capacity,
- the facility need methodology indicates a need for additional stations at the facility, and
- maintaining the status quo does not address the need for additional stations at the facility.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- 1. Total Renal Care of North Carolina, LLC d/b/a Franklin Township Dialysis shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the January 2018 SDR, Total Renal Care of North Carolina, LLC d/b/a Franklin Township Dialysis shall develop no more than two certified dialysis stations for a total of no more than 11 dialysis stations at Franklin Township Dialysis, which shall include any home hemodialysis training or isolation stations.**
 - 3. Total Renal Care of North Carolina, LLC d/b/a Franklin Township 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 11 stations, which shall include any isolation stations.**
 - 4. Total Renal Care of North Carolina, LLC d/b/a Franklin Township 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

TRCNC currently owns and operates FTD, a 9-station dialysis facility, in Macon County. The applicant proposes to add two dialysis stations, pursuant to the facility need methodology, to the existing facility for a total of 11 certified dialysis stations upon project completion.

Capital and Working Capital Costs

In Section F.1, pages 24-25, the applicant states that the capital costs for the project will total \$32,510 and provides a table with the estimated capital costs on page 24, as summarized below.

Projected Capital Costs

		Total Costs
Dialysis Machines	\$27,560	
Other Equipment/Furniture	\$ 4,950	
Total Capital Costs		\$32,510

The project does not involve any construction costs. In Section F, pages 26-27, the applicant states that FTD is an existing operational facility; therefore, there are no start-up or initial operating expenses.

Availability of Funds

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

Sources of Capital Cost Financing

Type		Total
Loans		
Accumulated reserves or OE *	\$32,510	\$32,510
Bonds		
Other (Specify)		
Total Financing	\$32,510	\$32,510

* OE = Owner's Equity

In Exhibit F-5, the applicant provides a letter dated March 15, 2018, from the DaVita Chief Accounting Officer, signed by William L. Hyland through procuracy, authorizing the project and committing \$32,510 for the development of the project.

Exhibit F-7 contains the Form 10-K for Davita, Inc. for the fiscal year ended December 31, 2016, showing consolidated figures of \$913,187,000 in cash and cash equivalents, \$18,741,257,000 in total assets and \$4,849,741,000 in total equity.

The applicant adequately demonstrates the availability of funds for the capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Section R, Forms A-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.

Franklin Township Dialysis Revenue and Expenses		
	OY1 (CY2020)	OY2 (CY2021)
In-Center Patient	38	38.5
PD Patients	14.5	15.5
In-Center Treatments	5,632	5,706
PD Treatments	2,149	2,297
Gross Patient Revenue	\$ 2,423,626	\$ 2,509,033
Medicare Adjustment from Gross	\$ 53,174	\$ 54,418
Net Patient Revenue	\$ 2,370,452	\$ 2,454,615
Average Net Revenue per IC and PD Patient	\$ 45,151	\$ 45,456
Total Operating Expenses	\$ 1,969,015	\$ 2,025,073
Average Operating Expense per IC and PD Patient	\$ 37,505	\$ 37,501
Net Income	\$ 401,437	\$ 429,541

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.

- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

TRCNC currently owns and operates FTD, a 9-station dialysis facility, in Macon County. The applicant proposes to add two dialysis stations, pursuant to the facility need methodology, to the existing facility for a total of 11 certified dialysis stations upon project completion.

On page 365, the 2018 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* FTD is located in Macon County; thus, the service area for this facility consists of Macon County. Facilities may also serve residents of counties not included in their service area.

According to the January 2018 SDR, FTD is the only provider of dialysis services in Macon County, as shown in the following table.

Macon County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
Franklin Township Dialysis	9	102.78%	4.1111

Source: January 2018 SDR, Table B.

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

“In Section B-2 and Section C of this application, we demonstrate the need that Franklin Township Dialysis has for adding stations. While adding stations at this facility does increase the number of stations in Macon County, it serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”

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

- The applicant demonstrates the need for the stations based on the facility need methodology.
- The applicant adequately demonstrates that the proposed stations are needed in addition to the existing or approved stations in Macon County.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

C

In Sections H and R, the applicant provides current and projected staffing for the proposed services as summarized in the following table.

POSITION	Current FTE Positions as of 12/31/17	OY2 PROJECTED FTE POSITIONS	OY2 PROJECTED ANNUAL SALARY	OY2 TOTAL PROJECTED SALARY
RN	2.0	2.0	\$72,120	\$144,240
LPN	0.0	0.0		\$0
Technician (Patient Care)	4.0	5.0	\$27,318	\$136,590
Medical Records	0.0	0.0		\$0
Administrator	1.0	1.0	\$81,955	\$81,955
Dietician	0.5	0.5	\$60,100	\$30,050
Social Worker	0.5	0.5	\$60,100	\$30,050
Home Training RN	1.0	1.0	\$72,120	\$72,120
Administrative Assistant	1.0	1.0	\$28,957	\$28,957
Bio-med Technician	0.5	0.5	\$44,802	\$22,401
Total	10.5	11.5		

Source: Sections H and R of the application.

Note: The Medical Director is a contract service

The assumptions and methodology used to project staffing are provided in Sections H and R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section R. In Section H, pages 32-33, the applicant describes the methods used to recruit or fill new positions and FTD's existing training and continuing education programs. In Section H.2, page 32, and Section I.3, page 36, the applicant identifies the current Medical Director. In Exhibit I-3, the applicant provides a letter from Samuel Fleming, M.D., indicating a commitment to continue to serve as Medical Director for the facility.

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

C

In Section I-1, pages 35-36, the applicant identifies the necessary ancillary and support services and explains how they will be made available. The applicant provides a table on page 35, as summarized below.

**Franklin Township Dialysis
 Ancillary and Support Services**

Services	Provider
(a) In-center dialysis/maintenance	On Premises
(b) Self-care training (performed in-center)	On Premises
(c) Home training	
(1) Hemodialysis	Asheville Kidney Center
(2) Peritoneal dialysis	On Premises
(3) Accessible follow-up program	On Premises
(d) Psychological counseling	On Premises
(e) Isolation-hepatitis	On Premises
(f) Nutritional counseling	On Premises
(g) Social work services	On Premises
(h) Acute dialysis in an acute care setting	Mission Hospital
(i) Emergency care	Mission Hospital
(j) Blood bank services	Mission Hospital
(k) Diagnostic and evaluation services	Mission Hospital
(l) X-ray services	Mission Hospital
(m) Laboratory services	DaVita Laboratory Services, Inc.
(n) Pediatric nephrology	Mission Hospital
(o) Vascular surgery	Mission Hospital
(p) Transplantation services	Wake Forest Baptist Medical Center
(q) Vocational rehabilitation counseling & services	NC Division of Vocational Rehabilitation Services
(r) Transportation	Macon County Transit

In Section I, pages 36-37, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-1 and 2.

The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

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

NA

The proposed project involves no construction. Therefore, Criterion (12) is not applicable to this review.

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

C

In Section L.7, page 48, the applicant provides the FTD historical payor mix percentages for the last full operating year, CY2017, as shown in the table below.

Payor Source	Total Patients	In-center Patients	PD Patients
Private Pay	0.0%	0.0%	0.0%
Medicare	15.0%	16.7%	10.0%
Medicaid	0.0%	0.0%	0.0%
Commercial Insurance	7.5%	3.3%	20.0%
Medicare / Commercial	42.5%	50.0%	20.0%
Medicare / Medicaid	30.0%	26.7%	40.0%
VA	5.0%	3.3%	10.0%
Other	0.0%	0.0%	0.0%
Total	100.0%	100.0%	100.0%

As shown in the table above, the applicant reports that 87.5% of the total patients at FTD had some or all of their services paid for by Medicare or Medicaid in CY 2017.

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
Macon	27%	51%	11%	17%	11%	18%
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 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states, and is representative of North Carolina patient profiles.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3(d), page 47, the applicant states:

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

In Section L.6, page 47, the applicant states that there have been no civil rights access complaints filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina within the last five years.

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

**Projected Payor Mix
 OY2**

Payor Source	Total Patients	In-center Patients	PD Patients
Private Pay	0.0%	0.0%	0.0%
Medicare	15.0%	16.7%	10.0%
Medicaid	0.0%	0.0%	0.0%
Commercial Insurance	7.5%	3.3%	20.0%
Medicare / Commercial	42.5%	50.0%	20.0%
Medicare / Medicaid	30.0%	26.7%	40.0%
VA	5.0%	3.3%	10.0%
Other	0.0%	0.0%	0.0%
Total	100.0%	100.0%	100.0%

Source: Application page 45

As shown in the table above, during the second full calendar year of operation, the applicant projects that 87.5% of the total dialysis patients will have all or part of their services paid for by Medicare and/or Medicaid, 7.5% will be paid through commercial insurance, and 5.0% through the Veterans Administration.

On page 45, the applicant states that the projected payor mix is based on the sources of patient payment that have been received by the existing facility in the last full operating year. No adjustment rate has been applied to this payor mix. The projected payor mix is reasonable and adequately supported for the following reasons:

- the applicant’s proposed patient origin is comparable to its historical patient origin, and
- the applicant bases the projected payor mix on the facility’s historical payor mix.

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

C

In Section L.4, page 47, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

C

In Section M, page 49, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

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

C

TRCNC currently owns and operates FTD, a 9-station dialysis facility, in Macon County. The applicant proposes to add two dialysis stations, pursuant to the facility need methodology, to the existing facility for a total of 11 certified dialysis stations upon project completion.

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” FTD is located in Macon County; thus, the service area for this facility consists of Macon County. Facilities may also serve residents of counties not included in their service area.

According to the January 2018 SDR, FTD is the only provider of dialysis services in Macon County, as shown in the following table.

Macon County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
Franklin Township Dialysis	9	102.78%	4.1111

Source: January 2018 SDR, Table B.

In Section N, page 50, the applicant describes the expected effects of the proposed services on competition in the service area and discuss 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 Franklin Township Dialysis will have no effect on competition in Macon 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 Franklin Township 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 member s and others involved in the dialysis process to receive services.”

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

- the cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits),
- quality services will be provided (see Section O of the application and any exhibits), and
- access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

C

In Section A.11, page 5, the applicant states that DaVita operates over 75 dialysis facilities located in North Carolina. Exhibit A-11 contains a list of the facilities.

Exhibit O-3 lists two facilities located in North Carolina and owned by DaVita that did not operate in compliance with the Medicare conditions of participation during the 18-month look-back period (September 1, 2016 through March 15, 2018). The applicant states that one of the facilities was back in compliance at the time of application submission. The other facility, Southeastern Dialysis Center-Wilmington, was recommended by the Agency to be back in compliance with CMS Conditions for Coverage, as of March 21, 2018. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 75 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the applicants provide 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 application is conforming with 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 a new ESRD facility.

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

-C- In Section C.2, page 14, the applicant provides the calculations used to arrive at the projected in-center patient census for the first two years of operation following the completion of the project.

At the end of OY1, the facility is projected to serve 38 in-center patients and at the end of OY2 the facility is projected to serve 39 in-center patients.

- OY1: 38 in-center patients = 3.45 patients per station per week, a utilization rate of 86.4% (38 patients / 11 stations = 3.45 / 4 = 0.8636 or 86.4%).
- OY2: 39 in-center patients = 3.55 patients per station per week, a utilization rate of 88.6% (39 patients / 11 stations = 3.55/4 = 0.886 or 88.6%).

The projected utilization of 3.45 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

-C- In Sections C.1 and C.7, pages 13-15 and 17-18, respectively, the applicant provides the assumptions and methodology used to project utilization of the facility.