

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 21, 2018

Findings Date: November 21, 2018

Project Analyst: Gregory F. Yakaboski

Team Leader: Fatimah Wilson

Project ID #: F-11599-18

Facility: Harrisburg Dialysis Center

FID #: 070392

County: Cabarrus

Applicant: Total Renal Care of North Carolina, LLC

Project: Add 9 stations for a total of 26 stations upon completion of this project and Project I.D. #F-11265-16 (relocate 8 stations to Hickory Ridge Dialysis)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Total Renal Care of North Carolina, LLC (TRC), d/b/a Harrisburg Dialysis proposes to add nine stations to the Harrisburg Dialysis facility for a total of 26 stations upon completion of this project and Project I.D. #F-11265-16 (relocate eight stations to Hickory Ridge Dialysis). Harrisburg Dialysis offers a peritoneal dialysis (PD) program however, the facility does not currently offer a home hemodialysis (HH) program. The parent company of TRC is DaVita, Inc. (DaVita).

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 the July 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there

is a deficit of three dialysis stations in Cabarrus County, therefore, the July 2018 SDR does not indicate a need for additional stations in Cabarrus County based on the county need methodology. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Harrisburg Dialysis in the July 2018 SDR is 3.4800 patients per station per week. This utilization rate was calculated based on 87 in-center dialysis patients and 25 certified dialysis stations as of December 31, 2017 (87 patients /25 stations = 3.48 patients per station per week). Application of the facility need methodology indicates that nine 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 12/31/17		87.0%
Certified Stations		25
Pending Stations		0
Total Existing and Pending Stations		25
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		87
In-Center Patients as of 6/30/17 (Jan 2018 SDR) (SDR1)		77
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	10
	Multiply the difference by 2 for the projected net in-center change	20
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17	0.2597
(ii)	Divide the result of Step (i) by 12	0.0216
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	0.2597
(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	109.5974
(v)	Divide the result of Step (iv) by 3.2 patients per station	34.2492
	and subtract the number of certified and pending stations to determine the number of stations needed	9.2492

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is nine stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2018 SDR. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add nine new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2018 SMFP which is applicable to this review: *Policy GEN-3: Basic Principles* on page 233 of the 2018 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

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

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4 (a), pages 9-10, Section K.1 (g), page 40, Section N, page 50, Section O, page 51, and Exhibits O-2 and O-3. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 10, Section C.3, page 16, Section L, pages 44-48, Exhibit L-3 and Section N, 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) and (d), page 11, Section C, pages 13-16, Section F, pages 24-29, Section K, pages 39-43 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 maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. The application is consistent with Policy GEN-3.

Conclusion

The Agency reviewed the:

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

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

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

C

TRC proposes to add nine stations to the Harrisburg Dialysis facility for a total of 26 stations upon completion of this project and Project I.D. #F-11265-16 (relocate eight stations to Hickory Ridge Dialysis). Harrisburg Dialysis offers a peritoneal dialysis program, however the facility does not currently offer a home hemodialysis program.

Patient Origin

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

The following tables illustrate current and projected patient origin for in-center (IC) patients and peritoneal dialysis (PD) patients.

Harrisburg Dialysis: Historical Patient Origin as of December 31, 2017

County	IC Patients	PD Patients
Cabarrus	74	12
Mecklenburg	11	0
Buncombe	1	5
Rowan	1	0
Stanly	0	1
Total	87	18

Source: Table on page 19 of the application.

Harrisburg Dialysis: Projected Patient Origin

County	OY1		OY2		County Patients as a % of Total	
	IC Patients	PD Patients	IC Patients	PD Patients	OY1	OY2
Cabarrus	75	14	80	15	83.2%	84.1%
Mecklenburg	11	4	11	4	14.0%	13.3%
Buncombe	1	0	1	0	0.9%	0.9%
Rowan	1	0	1	0	0.9%	0.9%
Stanly	0	1	0	1	0.9%	0.9%
Total	88*	19	93*	20	100.0%	100.0%

Source: Table on page 13 of the application.

*Note: This should read “85” and “90” respectively as the applicant did not subtract out 3 in-center patients from Mecklenburg County who will be transferring their care to Hickory Ridge Dialysis as of January 1, 2019 per Project ID #F-11265-16 (relocate 8 stations from Harrisburg Dialysis to Hickory Ridge Dialysis). In calculating the patient census on page 14 of the application TRC did correctly subtract out the 3 in-center patients from Mecklenburg County proposed to transfer to Hickory Ridge Dialysis.

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

Analysis of Need

In Section B.2, pages 6-7, the applicant states the application is filed pursuant to the facility need methodology in the 2018 SMFP utilizing data from the January and July 2018 SDRs. The facility need methodology shows a need for nine dialysis stations and the proposed project is for nine dialysis stations at Harrisburg Dialysis upon completion of this project and Project I.D. #F-11265-16 (relocate eight stations to Hickory Ridge Dialysis).

In Section C, pages 13-16, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 13-15, the applicant describes its need methodology assumptions for projecting utilization of the proposed facility as follows:

- The July 2018 SDR shows that Harrisburg Dialysis operated at a utilization rate of 87.0 percent (3.4 patients per station) as of December 31, 2017, and had 87 in-center patients. The applicant states that 74 of the 87 patients were residents of Cabarrus County with 13 patients residing in other counties.
- The applicant projects the first full operating year (OY1) of the project will be January 1, 2020 – December 31, 2020 (CY2020) and the second full operating year (OY2) will be January 1, 2021 – December 31, 2021 (CY2021).

- Project ID# F-11265-16 approved the relocation of 8 stations and projected transfer of 17 in-center patients (14 are Cabarrus County residents and 3 are Mecklenburg County residents) from Harrisburg Dialysis to Hickory Dialysis as of January 1, 2019. Therefore, after January 1, 2019, Harrisburg Dialysis will only have 10 patients residing in other counties (13-3 =10).
- TRC assumes the Cabarrus County in-center patient population will increase at the Cabarrus County Average Annual Change Rate (AACR) of 7.5% per year.
- The applicant projects no growth for patients who utilize the facility and live in other counties.

The information is reasonable and adequately supported because the proposed project complied with the facility need methodology.

Projected Utilization

In-Center Patients

The applicant’s utilization methodology, based on its stated assumptions, is provided on page 14 and is summarized in the following table.

Harrisburg Dialysis	In-Center Patients
Begin January 1, 2018 with 74 Cabarrus County patients	74
Project the Cabarrus County in-center patients forward to December 31, 2018, using the Five Year AACR for Cabarrus County.	$74 \times 1.075 = 79.55$
Subtract out the 14 in-center Cabarrus patients projected to transfer to Hickory Dialysis as of January 1, 2019.	$79 - 14 = 65$
Project the Cabarrus County in-center patients forward to December 31, 2019, using the Five Year AACR for Cabarrus County.	$65 \times 1.075 = 69.875$
Project the Cabarrus County in-center patients forward to December 31, 2020, using the Five Year AACR for Cabarrus County	$69.875 \times 1.075 = 75.12$
Add the 10 patients from other counties currently dialyzing at Harrisburg Dialysis. This is the patient census at the end of OY1.	$75.12 + 10 = \mathbf{85.12}$
Project the Cabarrus County in-center patients forward to December 31, 2019, using the Five Year AACR for Cabarrus County.	$75.12 \times 1.075 = 80.754$
Add the 10 patients from other counties currently dialyzing at Harrisburg Dialysis. This is the patient census at the end of OY2.	$80.754 + 10 = \mathbf{90.754}$

The applicant states on page 14 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2020) and OY2 (CY2021) the facility is projected to serve 85 and 90 in-center patients, respectively.

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

- OY1: 3.2692 patients per station per week, or 81.73% (85 patients / 26 stations = $3.2692/4 = 0.8173$ or 81.73%).
- OY2: 3.4615 patients per station per week, or 83.25% (90 patients/26 stations = $3.4615/4 = 0.8654$ or 86.54%).

The projected utilization of 3.2692 patients per station per week at the end of OY1 meets the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant starts with the 74 existing Cabarrus County patients.
- The Cabarrus County patients are projected to increase based on 7.5% per year which is the Five Year AACR for Cabarrus County as reported in Table D of the July 2018 SDR.
- The applicant projects no growth for patients who utilize the facility and live in other counties.

PD Patient Utilization

In Section C.1, page 15, the applicant provides the methodology and assumptions used to arrive at the projected peritoneal patient census for the first two years of operation following the completion of the project.

- OY 1 is projected to be CY2020; and OY 2 is projected to be CY2021.
- The applicant projects an increase of one patient per year during the growth period, beginning with 18 PD patient as of January 1, 2020 and reaching 20 patients by the end of OY2.
- The applicant states it is reasonable to assume that the Harrisburg Dialysis PD program will grow at a rate of at least one patient per year during the period of growth.
- The applicant averages the beginning and ending census for the year to reach an average number of patients per year for financial calculations.

The table below summarizes the beginning patient census on January 1, 2020 and its growth through the ending patient census on December 31, 2021, as presented by the applicant on page 15 of the application.

	# Patients, Beginning	# Patients, Ending	Average # Patients
Begin with the 18 PD patients utilizing Harrisburg Dialysis as of January 1, 2018	18	19	18.5
Subtract the two PD patients projected to transfer their care to Hickory Ridge Dialysis as of January 1, 2019	19-2= 17	18	17.5
OY1 [January 1, 2020-December 31, 2020]	18	19	18.5
OY2 [January 1, 2021-December 31, 2021]	19	20	19.5

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

- The applicant starts with the 18 existing Cabarrus County PD patients.
- The applicant projects growth at a rate of at least one patient per year during the period of growth.
- The applicant accounts for the 2 existing PD patients projected to transfer their care from Harrisburg Dialysis to Hickory Ridge Dialysis as of January 1, 2019.

Projected utilization for PD patients at Harrisburg Dialysis is reasonable and adequately supported based on the five-year AACR for Cabarrus County of 7.5% as reported in Table D of the July 2018 SDR.

Access

In Section C.3, page 16, 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.*” In Section L.1, page 45, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Projected Payor Mix

Payor Category	Harrisburg Dialysis Percent of Total Patients
Medicaid	1.9%
Medicare	23.3%
Medicare/Medicaid	23.3%
Medicare/Commercial	27.2%
Commercial Insurance	19.4%
VA Insurance	4.9%
Total	100.0%

Source: Table, page 45 of the application.

On page 45, the applicant states the projected payor mix is based on the payor mix during the last year of operation. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

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

NA

The applicant does not propose to reduce or eliminate a service, nor does the applicant propose to relocate a facility or 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

TRC proposes to add nine stations to the Harrisburg Dialysis facility for a total of 26 stations upon completion of this project and Project I.D. #F-11265-16 (relocate eight stations to Hickory Ridge Dialysis).

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

Maintain the Status Quo- The applicant states that maintaining the status quo is not an effective alternative because of the growth rate at the facility.

Relocate Stations from another DaVita Facility- DaVita has two other operational facilities in Cabarrus County, both of which are operating at over 80.0% capacity. Patients presently being served by these two other facilities would be negatively impacted if stations were relocated from these facilities.

On page 23, the applicant states that its proposal is the most effective alternative because the proposed project will address both the issues of growth and access to the facility. Developing a third shift is inconvenient for patients.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Total Renal Care of North Carolina, LLC shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the July 2018 SDR, Total Renal Care of North Carolina, LLC shall develop no more than 9 additional dialysis stations for a total of no more than 26 certified stations at Harrisburg Dialysis upon completion of this project and Project I.D. #F-11265-16 (relocate eight stations to Hickory Ridge Dialysis), which shall include any home hemodialysis training or isolation stations.**
 - 3. Total Renal Care of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

TRC proposes to add nine stations to the Harrisburg Dialysis facility for a total of 26 stations upon completion of this project and Project I.D. #F-11265-16 (relocate eight stations to Hickory Ridge Dialysis).

Capital and Working Capital Costs

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

Dialysis Machines	\$7,150
Equipment/furniture excluding dialysis machines	\$4,698
Total	\$11,848

In Section F.1, page 24, the applicant provides the assumptions used to project the capital cost.

In Section F.10, pages 26-27, the applicant states that there will be no start-up costs since Harrisburg Dialysis is an existing facility.

Availability of Funds

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

Sources of Capital Cost Financing

Type	DaVita Inc.	Total
Accumulated reserves or OE *	\$11,848	\$11,848
Total Financing	\$11,848	\$11,848

* OE = Owner's Equity

On page 26, the applicant states that Total Renal Care of North Carolina, LLC is wholly owned by DaVita Inc. In Exhibit F-5, the applicant provides a letter dated September 17, 2018 from the Chief Accounting Officer of DaVita, Inc. confirming that DaVita Inc. is the parent and 100% owner of Total Renal Care of North Carolina, LLC. The letter states,

“This letter will confirm that DaVita Inc. has committed cash reserves in the total sum of \$11,848 for the project capital expenditure. DaVita, Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to Total Renal Care of North Carolina, LLC.”

Exhibit F also includes a copy of the United States Securities and Exchange Commission Form 10-K for DaVita, Inc. for the fiscal year ended December 31, 2017. Form 10-K, page F-6, shows DaVita, Inc. having “Cash and cash equivalents” of \$508,234,100 and a “Total equity” balance of \$4,886,066,000 as of December 31, 2017.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	1 st Full Fiscal Year	2 nd Full Fiscal Year
Total Treatments*	14,894	15,858
Total Gross Revenues (Charges)	\$6,446,553	\$6,854,181
Total Net Revenue	\$6,287,538	\$6,684,660
Average Net Revenue per treatment	\$422.15	\$421.53
Total Operating Expenses (Costs)	\$4,401,726	\$4,650,866
Average Operating Expense per treatment	\$295.54	\$293.28
Net Income	\$1,885,812	\$2,033,794

*Source: Form C

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

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

TRC proposes to add nine stations to the Harrisburg Dialysis facility for a total of 26 stations upon completion of this project and Project I.D. #F-11265-16 (relocate eight stations to Hickory Ridge Dialysis).

On page 365 the 2018 SMFP defines the service area for dialysis stations as “*a dialysis station’s service area is the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate*”

dialysis station planning area.” Thus, the service area for this facility consists of Cabarrus County. Facilities may also serve residents of counties not included in their service area.

DaVita operates all four of the dialysis facilities in Cabarrus County. The utilization for the four (2 existing and 2 approved) Cabarrus County dialysis facilities are shown in the table below:

Existing and Approved Cabarrus County Dialysis Facilities

Dialysis Facility	Owner	Certified Stations 12/31/17	CON Issued Not Certified	% Utilization	Patients Per Station
Cannon Dialysis*	DaVita	0	11	0.0%	0.0000
Copperfield Dialysis**	DaVita	27	-27	84.26%	3.3704
Copperfield Dialysis**	DaVita	0	29	0.0%	0.0000
Harrisburg Dialysis	DaVita	25	-8	87.0%	3.4800
Hickory Ridge***	DaVita	0	10	0.0%	0.0000

Source: July 2018 SDR, Table B.

*Cannon Dialysis is an approved new facility per Project ID# F-11452-18 [Develop a new 11-station facility by relocating eight dialysis stations from Dialysis Care of Kannapolis in Rowan County and relocating three dialysis stations from North Charlotte Dialysis in Mecklenburg County]. A certificate of need was issued on June 26, 2018.

**Copperfield Dialysis is listed twice in the table above because it is in the process of relocating sites per Project ID#F-11019-15 [Relocate the facility to a new location and add four stations relocated from North Charlotte Dialysis Center for a total of 31 stations upon completion of this project and Project I.D. #F-10109-13, (add 6 stations by relocation from Dialysis Care of Kannapolis in Rowan County]

***Hickory Ridge is an approved new facility per Project ID# F-11265-16 [Develop a new 10-station facility by relocating 8 stations from Harrisburg Dialysis and 2 stations from Copperfield Dialysis]

As shown in the table above, both of the operational dialysis facilities operated at utilization rates of 84% or higher.

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

“Adding stations at this facility does not increase the number of stations in Cabarrus County it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”

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

- The applicant adequately demonstrates that the proposed addition of nine dialysis stations at Harrisburg Dialysis is needed in addition to the existing stations.

- The applicant adequately demonstrated the need for the stations based on the Cabarrus County DaVita facility's patients' needs.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section H.1, page 31, the applicant provides the current staffing for the facility, and states that Harrisburg Dialysis is not projected to add any full time equivalent (FTE) positions as a result of this proposal. The applicant states the facility currently staffs 19.5 FTE positions and will have a staff of 19.5 FTEs upon project completion. In addition, the applicant provides projected direct care staff in OY 2 in Section H.7, page 34.

The assumptions and methodology used to project staffing are provided in Section H.1, page 31 and Sections H.6 and H.7, page 34. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, pages 32-33, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibits H-2, H-3 and H-4, the applicant provides supporting documentation. In Section I.3 page 35, the applicant identifies the medical director. In Exhibit I, the applicant provides a letter from the current medical director indicating an interest in continuing to serve as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section I.1, page 35, the applicant identifies the ancillary and support services necessary for the proposed services, as shown in the table below.

HARRISBURG DIALYSIS Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	Harrisburg Dialysis
Self-care training (in-center)	Harrisburg Dialysis
Home training HH PD	DC Kannapolis Harrisburg Dialysis
Accessible follow-up program	Harrisburg Dialysis
Psychological counseling	Harrisburg Dialysis
Isolation – hepatitis	Harrisburg Dialysis
Nutritional counseling	Harrisburg Dialysis
Social Work services	Harrisburg Dialysis
Acute dialysis in an acute care setting	CMC Northeast
Emergency care	CMC Northeast
Blood bank services	CMC Northeast
Diagnostic and evaluation services	CMC Northeast
X-ray services	CMC Northeast
Laboratory services	DaVita Laboratory Services
Pediatric nephrology	CMC Northeast
Vascular surgery	CMC Northeast
Transplantation services	CMC Northeast
Vocational rehabilitation & counseling	NC DHHS Div of Vocational Rehab Services
Transportation	DSS and Cabarrus County Transportation Services

On page 35, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-1.

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 I-3.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

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

NA

The applicant does not propose to construct any new space nor renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

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

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 48, the applicant provides the historical payor mix during January 1, 2017 to December 31, 2017 at Harrisburg Dialysis for the proposed services, as shown in the table below.

Historical Payor Mix

Payor Category	Harrisburg Dialysis Percent of Total Patients
Medicaid	1.9%
Medicare	23.3%
Medicare/Medicaid	23.3%
Medicare/Commercial	27.2%
Commercial Insurance	19.4%
VA Insurance	4.9%
Total	100.0%

Source: Table, page 48 of the application.

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**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Cabarrus	13%	51%	34%	11%	7%	10%
Mecklenburg	11%	52%	53%	12%	6%	12%
Rowan	17%	51%	28%	17%	11%	13%
Buncombe	19%	52%	16%	14%	10%	11%
Stanly	19%	15%	19%	13%	12%	12%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. 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., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (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. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

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.

The Agency reviewed the:

- Application
- Exhibits to the application

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 <https://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, page 47, the applicant states,

“Harrisburg Dialysis Center 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 during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.1, page 45, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	Harrisburg Dialysis Percent of Total Patients
Medicaid	1.9%
Medicare	23.3%
Medicare/Medicaid	23.3%
Medicare/Commercial	27.2%
Commercial Insurance	19.4%
VA Insurance	4.9%
Total	100.0%

Source: Table, page 45 of the application.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 23.3% of total services will be provided to Medicare patients, 1.9% to Medicaid patients, 23.3% to Medicare/Medicaid patients and 27.2% to Medicare/Commercial patients.

On page 45, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based “*on the sources of patient payment that have been received by existing facility in the last full operating year.*”

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.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

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 will 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

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

TRC proposes to add nine stations to the Harrisburg Dialysis facility for a total of 26 stations upon completion of this project and Project I.D. #F-11265-16 (relocate eight stations to Hickory Ridge Dialysis).

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

DaVita operates all four of the dialysis facilities in Cabarrus County. The utilization for the four (2 existing and 2 approved) Cabarrus County dialysis facilities are shown in the table below:

Existing and Approved Cabarrus County Dialysis Facilities

Dialysis Facility	Owner	Certified Stations 12/31/17	CON Issued Not Certified	% Utilization	Patients Per Station
Cannon Dialysis*	DaVita	0	11	0.0%	0.0000
Copperfield Dialysis**	DaVita	27	-27	84.26%	3.3704
Copperfield Dialysis**	DaVita	0	29	0.0%	0.0000
Harrisburg Dialysis	DaVita	25	-8	87.0%	3.4800
Hickory Ridge***	DaVita	0	10	0.0%	0.0000

Source: July 2018 SDR, Table B.

*Cannon Dialysis is an approved new facility per Project ID# F-11452-18 [Develop a new 11-station facility by relocating eight dialysis stations from Dialysis Care of Kannapolis in Rowan County and relocating three dialysis stations from North Charlotte Dialysis in Mecklenburg County]. A certificate of need was issued on June 26, 2018.

**Copperfield Dialysis is listed twice in the table above because it is in the process of relocating sites per Project ID#F-11019-15 [Relocate the facility to a new location and add four stations relocated from North Charlotte Dialysis Center for a total of 31 stations upon completion of this project and Project I.D. #F-10109-13, (add 6 stations by relocation from Dialysis Care of Kannapolis in Rowan County)]

***Hickory Ridge is an approved new facility per Project ID# F-11265-16 [Develop a new 10-station facility by relocating 8 stations from Harrisburg Dialysis and 2 stations from Copperfield Dialysis]

In Section N, page 50, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 50, the applicant states:

“The expansion of Harrisburg Dialysis Center will have no effect on competition in Cabarrus 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 Harrisburg Dialysis Center will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”

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

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

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

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

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

C

In Section A, page 5, the applicant states DaVita operates more than 85 dialysis facilities in North Carolina. Exhibit A contains a list of the DaVita dialysis facilities located in North Carolina.

In Section O, page 51, and Exhibit O-3 the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these facilities, Southeastern Dialysis Center-Wilmington and Goldsboro South Dialysis. The applicant states that all of the problems have been corrected and that Southeastern Dialysis Center-Wilmington was back in compliance as of March 21, 2018 and that Goldsboro South Dialysis was back in compliance as of November 20, 2017. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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 13-16, the applicant demonstrates that Harrisburg Dialysis will serve 85 in-center patients at the end of OY1 (CY2020) for a utilization rate of 81.73% or 3.2692 patients per station per week ($85 \text{ patients} / 26 \text{ stations} = 3.2692 / 4 = 0.8173$ or 81.73%). 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. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.