

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 25, 2017

Findings Date: August 25, 2017

Project Analyst: Bernetta Thorne-Williams

Team Leader: Lisa Pittman

Project ID #: K-11352-17

Facility: Bunn Dialysis

FID #: 170241

County: Franklin

Applicant: Total Renal Care of North Carolina, LLC

Project: Develop a new 10-station dialysis facility in Franklin County by relocating ten stations from DC Franklin County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

DaVita, Inc. is the parent company of Total Renal Care of North Carolina, LLC (TRC). Total Renal Care of North Carolina, LLC d/b/a Bunn Dialysis proposes to develop a new 10-station dialysis facility in Bunn, in Franklin County by relocating ten dialysis stations from Dialysis Care of Franklin County (DC Franklin County). The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, Bunn Dialysis will be certified for 10 dialysis stations and DC Franklin County will be certified for 17 dialysis stations.

Need Determination

The applicant is proposing to relocate existing dialysis stations within Franklin County, therefore there are no need methodologies in the 2017 State Medical Facilities Plan (2017 SMFP) applicable to this review.

Policies

There are two policies in the 2017 SMFP that are applicable to this review: *Policy ESRD-2 Relocation of Dialysis Stations*, on page 27 and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on page 33.

POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to develop a new 10-station dialysis facility, Bunn Dialysis, in Bunn, by relocating ten existing dialysis stations from DC Franklin County. The existing facility is and the proposed facility will be located in Franklin County, thus there will be no change in the dialysis station inventory in Franklin County. Therefore, the application is consistent with Policy ESRD-2.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

The proposed capital expenditure is greater than \$2 million, but less than \$5 million. In Section B-5, pages 11-12, Section K-1, pages 42-43, and Exhibits B-4 and K-1(d) the applicant describes how it will assure improved energy efficiency and water conservation. Therefore, the application is conforming to Policy GEN-4.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the applicable policies in the 2017 SMFP.

Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to develop a new 10-station dialysis facility in Bunn by relocating ten dialysis stations from DC Franklin County. The existing facility is and the proposed facility will be located in Franklin County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, Bunn Dialysis will be certified for 10 dialysis stations and DC Franklin County will be certified for 17 dialysis stations.

Patient Origin

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

Bunn Dialysis will be a new facility in Franklin County and therefore has no existing patient origin.

In Section C.1, page 13, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion for in-center (IC) patients. The applicant proposes to serve peritoneal dialysis patients (PD), but not home hemodialysis patients (HH), as illustrated in the following table:

BUNN DIALYSIS PROJECTED PATIENT ORIGIN						
	OY1 CY2019		OY2 CY2020		Percent of Total	
	IC	PD	IC	PD	OY1	OY2
Franklin*	32 (30)	2	32 (30)	3	94.4%	94.6%
Nash	2	0	2	0	5.6%	5.4%
Total	34 (32)	2	34 (32)	3	100.0%	100.0%

*Analyst adjustment. See below

The applicant provides a total of 34 letters of support from patients currently dialyzing at other DaVita facilities indicating a willingness to consider transferring their care to the proposed facility. However, 2 of the 34 letters are from patients currently receiving peritoneal dialysis and 32 of the letters are from in-center patients. Of those 32 in-center patient letters; 30 patients currently reside in Franklin County and two of those patients reside in Nash County. Thus, the beginning in-center census for Bunn dialysis consisting of Franklin County patients is 30 patients and not 32 patients as the applicant states on page 13, plus the two in-center patients from Nash County, therefore the total in-center patients for OY1 and OY2 is 32 patients and not 34 patients.

See pages 13-15 for the assumptions and methodology used to project patient origin including a summary of the patient support letters found in Exhibit C-1.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.2, pages 15-16, the applicant states that it determined a need for a new dialysis facility in the southern part of Franklin County based on the fact that 32 in-center

patients currently receiving services at TRC facilities live in the southern part of Franklin County. Additionally, the applicant identified two PD patients that are currently served by another facility, but live in a ZIP Code area that is closer to the southern part of Franklin County.

Based on the signed letters from patients currently dialyzing at DaVita operated facilities in other areas of Franklin and Wake counties, the applicant concluded that the proposed new facility will be located closer to where a significant number of its patients reside. In Section C.2, page 16, the applicant states:

“In order to make the travel to dialysis – three times a week for in-patients and monthly for PD patients -- more convenient, it was determined that Total Renal Care of North Carolina, LLC needs to provide a dialysis center nearer to their homes for better access to their dialysis services and support.”

See Exhibit C-1 which contains 34 patient letters of support which state:

“I fully support this new dialysis facility ... to be built in Bunn. ... Having my dialysis treatments at Bunn Dialysis would be more convenient for me. I could travel between home and that location more easily and quickly, which would save me time and money.”

Projected Utilization

In Section C.1, pages 13-15, the applicant provides the assumptions and methodology used to project utilization for the proposed facility. The assumptions and methodology are summarized as follows:

- The applicant states that it received 32 letters of support from in-center patients dialyzing at DaVita operated facilities in Franklin and Wake counties indicating their willingness to consider transferring their care to the proposed facility. Thus, the in-center patients and the stations are projected to come from DC Franklin County and the two PD patients are projected to come from Wake Forest Dialysis, Wake County.
- The applicant assumes that the 30 in-center patients who are residents of Franklin County will increase at a rate commensurate with Franklin County’s Five Year Average Annual Change Rate (AACR) of 1.0%, as published in Table B of the January 2017 Semi-Annual Dialysis Report (SDR), through the second operating year.
- The applicant states two in-center patients who have expressed an interest in transferring their care to the proposed new facility are residents of Nash County.

- The applicant states the following concerning those patients who have expressed an interest in transferring their care to the proposed facility:
 - one in-center patient resides in Bunn (27508 ZIP Code);
 - twenty-three reside in Louisburg (27549 Zip Code)
 - five reside in Youngsville (27596 Zip Code);
 - one resides in Castalia (27816 Zip Code); and,
 - two reside in Spring Hope (27882).

In Section C.1, page 14, the applicant provides the calculations used to arrive at the projected in-center patient census for Operating Years (OY) 1 (CY2019) and 2 (CY2020).

Bunn Dialysis	In-Center Patients
January 1, 2019, the beginning of Operating Year 1, will begin with 32 in-center patients who have transferred their care from other DaVita dialysis facilities.	32
Growth is projected during OY1 by multiplying the beginning census of 32 Franklin County patients by the Franklin County Five Year AACR of 0.10%.	$32 \times 1.001 = 32.032$
The applicant then adds the two patients from in Nash County. This is the ending census for OY1, December 31, 2019.	$32.032 + 2 = 34.032$
Growth is projected again for OY2 by multiplying the Franklin County in-center patients by the Franklin County Five Year AACR of 0.10%.	$32.032 \times 1.001 = 32.064$
The applicant then adds the two patients from in Nash County. This is the ending census for OY2, December 31, 2020.	$32.064 + 2 = 34.064$

However, the calculations provided by the applicant include all 32 patients currently receiving care at DaVita operated facilities in Franklin and Wake Counties. However, two of those patients reside in Nash County and therefore cannot be included in the projected growth for Franklin County. Then the applicant added those two patients from Nash County back into the end of year census, thereby counting those patients twice, as illustrated in the table above.

The project analyst calculated the projected growth for Franklin County using only those patients that reside in Franklin County (one from Castalia, five from Youngsville, 23 from Louisburg and one from Bunn) for a total of 30 in-center patients and then added the two patients from Nash County into the census for the facility, as illustrated below.

Bunn Dialysis	In-Center Patients
January 1, 2019, the beginning of Operating Year 1, will begin with 32 in-center patients who have transferred their care from other DaVita dialysis facilities.	32
Growth is projected during OY1 by multiplying the beginning census of 30 Franklin County by the Franklin County Five Year AACR of 1.0%.	$30 \times 1.001 = 30.03$
The applicant then adds the two patients from in Nash County. This is the ending census for OY1, December 31, 2019.	$30.03 + 2 = 32.03$
Growth is projected again for OY2 by multiplying the Franklin County in-center patients by the Franklin County Five Year AACR of 1.0%.	$30.03 \times 1.001 = 30.06$
The applicant then adds the two patients from in Nash County. This is the ending census for OY2, December 31, 2020.	$30.06 + 2 = 32.06$

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 2019) and OY2 (CY2020) the facility is projected to serve 32 in-center.

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

- OY1: 3.2 patients per station per week, or 80% ($32 \text{ patients} / 10 \text{ stations} = 3.2/4 = 0.8$ or 80%).
- OY2: 3.2 patients per station per week, or 80% ($32 \text{ patients} / 10 \text{ stations} = 3.2/4 = 0.8$ or 80%).

The projected utilization of 3.2 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 based on reasonable and adequately supported assumptions regarding continued growth.

Peritoneal and Home Hemodialysis

The applicant proposes to offer peritoneal dialysis, but will not offer home hemodialysis training and support services at the proposed facility. The applicant provides two letters of support from patients currently receiving peritoneal dialysis and support at Wake Forest Dialysis who have expressed an interest in transferring their care to the proposed facility. In Section C, page 15, the applicant provides its assumptions and methodology for its peritoneal dialysis patients. In Section I.1, page 38, the applicant states that home hemodialysis training and support will be provided at Wake Forest Dialysis.

Access to Services

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 addition, the applicant projects, in Section L.1, page 49, that 87.8% of its patients at Bunn Dialysis will have some or all of their expenses paid by either Medicare or Medicaid. The applicant states that the projected payor mix for the proposed facility is based on sources of payment for DaVita operated facilities in Franklin County for the last full operating year. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed dialysis services at Bunn Dialysis. Therefore, the application is conforming to this criterion.

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

The applicant proposes to develop a new ten station dialysis facility in Bunn by relocating ten dialysis stations from DC Franklin County. The existing facility is and the proposed facility will be located in Franklin County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, Bunn Dialysis will be certified for 10 dialysis stations and DC Franklin County will be certified for 17 dialysis stations (27-10=17).

In Section D.1, pages 23-24, the applicant discusses how the needs of dialysis patients at DC Franklin County will continue to be met following the relocation of stations to Bunn Dialysis. In Section D.1, page 23, the applicant states that as of June 30, 2016, as reported in the January 2017 SDR, there were 77 in-center dialysis patients at DC Franklin County dialyzing on 27 dialysis stations, for a utilization rate of 71.30%. In addition, the applicant states that 67 of the 77 in-center patients lived in Franklin County and that 10 lived outside Franklin County.

In Section C.1, page 13, the applicant projects that 32 in-center patients currently receiving services at DC Franklin County (30 patients who reside in Franklin County and two who reside in Nash County) will transfer to Bunn Dialysis.

The applicant assumes that the number of in-center patients at DC Franklin County who live in Franklin County will increase at 0.10% per year based on the Five Year AACR for Franklin County, as reported in Table B of the January 2017 SDR. The applicant assumes that no growth will occur for the two in-center patients living outside of Franklin County.

The applicant provides conflicting information in Section C and Section D. In Section C, the applicant projects that 32 Franklin County residents and two Nash County residents will transfer their care to the proposed Bunn facility (page 13). However, a review of the support letters submitted by patients who have expressed an interest in transferring their care to the proposed facility determined that there are 30 patients from Franklin County and two patients from Nash County who propose to transfer their in-center care to the proposed facility for a total of 32 patients. (see Exhibit C for patient letters of support)

However, in Section D, page 23, the applicant states that it projects at least 28 in-center patients from DC Franklin will transfer their care to the proposed facility (26 patients from Franklin County and two patients from Nash County). The project analyst based its calculations on the information provided in Section C and Exhibit C, as illustrated in the table below.

In Section D.1, page 24, the applicant calculates the in-center patient census for DC Franklin County starting July 1, 2016 through OY1 (CY2019) and OY2 (CY2020), as follows:

DC Franklin County Dialysis	In-Center Patients
Beginning census for July 1, 2016 for Franklin County patients only, increased by half the Five Year AACR for Franklin County of .05%. Add 10 patients from outside Franklin County to arrive at the ending census for December 31, 2016.	$67 \times 1.0005 = 67.0335 + 10 = 77.0335$
Franklin County patient census for CY2017 is projected forward by 0.10%, the Five Year AACR for Franklin County. Add 10 patients from outside Franklin County to arrive at ending census for December 31, 2017	$67.0335 \times 1.001 = 67.1005 + 10 = 77.1005$
Franklin County patient census for CY2018 is projected forward by 0.01% Five Year AACR for Franklin County. Add 10 patients from outside Franklin County to arrive at ending census for December 31, 2018.	$67.1005 \times 1.001 = 67.16768 + 10 = 77.1676$
OY1 (CY2019) Franklin County patient census for CY2019 is projected forward by 1.001%, the Five Year AACR for Franklin County. (After subtracting 30 Franklin County patients who are projected to transfer to the proposed Bunn Dialysis facility). And two patients from Nash County ($10 - 2 = 8$). Add 8 patients from Nash County to arrive at ending census for December 31, 2019.	$67.16768 - 30 = 37.16768 \times 1.001 = 37.2048 + 8 = 45.2034$
OY2 (CY2020) Franklin County patient census for CY2020 is projected forward by 1.001%, the Five Year AACR for Franklin County. Add 8 patients from Nash County to arrive at ending census for December 31, 2020.	$37.2048 \times 1.001 = 37.2420 + 8 = 45.2420$

The applicant states projected patients for OY1 and OY2 are rounded down to the nearest whole number. Thus, DC Franklin County is projected to have 45 in-center patients at the end of OY1 dialyzing on 17 stations for a utilization rate of 66.2 %, or 2.6 patients per station per week ($45 \text{ patients} / 17 \text{ stations} = 2.6/4 = 0.6617$ or 66.2%). This utilization for DC Franklin County is consistent with its historical utilization as reported in the most recent SDR (July 2017). The applicant states the following on page 24:

“Given this projected growth of the in-center patient population, the needs of the population presently served at this location will be adequately met. ...”

Conclusion

The applicant demonstrates that the needs of the populations presently served at DC Franklin County will continue to be adequately met following the proposed relocation of ten dialysis stations from the facility to Bunn Dialysis and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

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

CA

In Section E.1, page 25, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Maintaining the status quo – the applicant concluded that maintaining the status quo did not meet the growing need for dialysis services in the southern portion of Franklin County. Therefore, this is not an effective alternative.
- Locating the facility in another area of Franklin County – the applicant states that it analyzed the patient population currently being served at DaVita operated facilities in Franklin County and determined that southern Franklin County was in need of a dialysis center, as based on the letters of support. Building the facility in another part of the county would not provide better geographic access to patients currently being served. Therefore, this is not an effective alternative.

After considering the above alternatives, the applicant states that development of the new Bunn Dialysis facility would reduce the transportation demands faced by existing patients and increase the patients' quality of life and compliance with treatment schedules. Therefore, the proposed project is the most effective alternative to meet the identified need.

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

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC d/b/a Bunn Dialysis shall materially comply with all representations made in the certificate of need application.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Bunn Dialysis shall relocate no more than ten dialysis stations from DC Franklin County for a total of no more than 10 dialysis stations at Bunn Dialysis.**
- 3. Total Renal Care of North Carolina, LLC d/b/a Bunn Dialysis shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.**
- 4. Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify ten dialysis stations at Dialysis Care of Franklin County for a total**

of no more than 17 dialysis stations at Dialysis Care of Franklin County upon project completion.

- 5. Prior to the issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a Bunn Dialysis shall provide documentation of a service agreement between Bunn Dialysis and Wake Forest Dialysis for Wake Forest Dialysis to provide home hemodialysis training and support services.**
 - 6. Total Renal Care of North Carolina, LLC d/b/a Bunn Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new 10-station dialysis facility in Bunn by relocating ten dialysis stations from DC Franklin County.

Capital and Working Capital Costs

In Section F.1, page 27, the applicant provides the capital cost of the project as summarized in the following table:

Site Costs	\$47,088
Construction Contract	\$1,251,833
Dialysis Machines	\$165,360
Water Treatment Equipment	\$146,360
Equipment/Furniture	\$425,532
Architect & Engineering Fees	\$94,000
Total Capital Costs	\$2,130,173

In Section F.10, pages 29-30, and Section F.11, page 30, the applicant estimates start-up expenses of \$195,033 and initial operating expenses of \$787,126, respectively, for a total working capital \$982,159.

Availability of Funds

In Section F.2, page 28, the applicant states that accumulated reserves/owner's equity will be used to finance the project's capital costs. In Section F.13, page 31, the applicant states that the working capital costs will be financed with cash reserves. Exhibit F-5 contains a letter from DaVita Inc.'s Chief Accounting Officer, dated May 15, 2017, confirming DaVita's commitment to funding the project's capital costs and working capital costs with cash reserves.

In Exhibit F-7, the applicant provides a copy of DaVita HealthCare Partners, Inc. (DaVita) United States Securities and Exchange Commission Form 10-K for the fiscal year ended December 31, 2016. As of December 31, 2016, DaVita had \$913,187,000 in cash and cash equivalents, \$18,741,257,000 in total assets, and \$5,822,999,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

Financial Feasibility

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

	Operating Year 1	Operating Year 2
Total Treatments	5,309	5,309
Total Gross Revenues (Charges)	\$1,676,878	\$1,706,463
Total Net Revenue	\$1,624,533	\$1,654,119
Total Operating Expenses (Costs)	\$1,574,252	\$1,602,064
Net Income	\$50,281	\$52,054

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. In Section H.1, page 34, the applicant provides projected staffing and salaries. Form A in Section R, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

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

Conclusion

In summary, the applicant adequately demonstrates the financial feasibility of the project is based on reasonable projections of revenues (charges) and operating costs. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to develop a new 10-station dialysis facility in Bunn by relocating ten dialysis stations from DC Franklin County. The existing facility is and the proposed facility will be located in Franklin County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, Bunn Dialysis will be certified for 10 dialysis stations and DC Franklin County will be certified for 17 dialysis stations.

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

The January 2017 SDR indicates there are two dialysis facility in Franklin County with one of those facilities still under development, as follows:

**Franklin County Dialysis Facilities
 June 30, 2016**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Dialysis Care of Franklin Country	DaVita	77	Louisburg	27	0	71.30%
FMC Tar River	Fresenius Medical Care	Under development – New 10 station facility				

Source: January 2017 SDR

As illustrated above, there are two existing dialysis facilities located in Franklin County with one of those facilities being under development, as of the January 2017 SDR. Of those two facilities, one facility is operated by DaVita and the other facility is operated by Fresenius. The proposed site for Bunn Dialysis is in the southern part of Franklin County. DC Franklin County operated with a utilization rate over 70. % as of June 30, 2016. The

one facility operated by Fresenius had three patients to report as of December 31, 2016 because that is the day the facility was certified.

The applicant is not increasing the number of dialysis stations in Franklin County, rather it is relocating 10 of them to develop a new facility that is closer to patients living in the southern part of the area where the new facility will be located. Therefore, the applicant is not duplicating services, rather it is proposing to create a new facility to better serve existing patients using existing stations.

In Section C.1, page 14, the applicant demonstrates that Bunn Dialysis will serve a total of 32 in-center patients on 10 stations at the end of the first operating year, which is 3.2 patients per station per week, or a utilization rate of 80% ($32/10 = 3.2$; $3.2/4 = 0.80$ or 80%). The applicant provides documentation in Exhibit C-1 from 32 in-center patients at its Franklin County facility indicating their willingness to consider transferring to Bunn Dialysis upon project completion because its location would be more convenient. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates the need to relocate stations to develop a new dialysis facility in Franklin County. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on the needs of the population presently served at DC Franklin County, found in Criterion (3a), is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Franklin County. Consequently, the application is conforming to this criterion.

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

C

The applicant provides the projected staffing for Bunn Dialysis in Section H.1, page 34, as follows:

Position	Projected Number of FTEs
Medical Director*	
Registered Nurse	2.0
Patient Care Technician (PCT)	4.0
Administrator	1.0
Dietitian	0.5
Social Worker	0.5
Home Training RN	0.5
Administrative Assistant	1.0
Biomedical Technician	0.3
Total	9.8

*The Medical Director is an independent contractor, not an employee of the facility.

In Section H.3, pages 35-36, the applicant states that it will fill positions by using a DaVita Teammate Recruiter, the Teammate Referral Program, and its Student Internship Program. In addition, the applicant states that it provides a wide range of benefits and competitive salaries to attract candidates for positions.

In Section H.7, page 37, the applicant provides the projected Direct Care Staff Hours for OY2. In Section H.2, page 35, the applicant states that the Medical Director for Bunn Dialysis will be Dr. Li-Kun Tu, a board certified nephrologist. In Exhibit I-3, the applicant provides a letter signed by Dr. Tu, dated May 11, 2017, confirming his commitment to serve as Medical Director. The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section I, page 38, the applicant discusses the provision of necessary ancillary and support services to be provided for the proposed facility and provides a list of service providers. Additionally on page 38, the applicant states that peritoneal dialysis services will be provided at Bunn Dialysis, however, home hemodialysis will be provided by Wake Forest Dialysis. Although the applicant indicates that a service agreement for this service is provided in Exhibit I-1, a service agreement for those services at Wake Forest Dialysis was

not included in the application. Therefore, prior to the issuance of the certificate of need the applicant shall provide documentation that Wake Forest Dialysis will provide home hemodialysis training and support.

The applicant provides documentation regarding coordination with the existing health care system in Exhibits I-1 and I-2 including letters from several providers such as DaVita Laboratory Services, Inc., Karts Transportation Authority, Duke Surgery for vascular services, Duke Health for transplant services and Maria Parham Health for acute care services. The information in Section I and Exhibits I-1, I-2 and I-3 is reasonable and adequately supports a finding of conditional conformity with this criterion, subject to Criterion 4, Condition #5 of these findings.

- (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

- (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

- (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.

C

In Section K.2, page 43, the applicant states, the proposed facility is projected to consist of a 3,366 square foot treatment space which will include space for an isolation room. The applicant provides line drawings of the proposed facility in Exhibit K-1(a). The drawing depicts an 8,500 square foot facility, including office space, two peritoneal dialysis rooms, nine dialysis stations located in open space and one isolation dialysis station in an enclosed room, for a total of 10 in-center stations. In Section F.1, page 27, the applicant lists its projected costs, including \$47,088 for site work, \$1,251,833 for construction and \$831,252 for miscellaneous costs including dialysis machines, water treatment equipment, furniture, and architect/engineering fees for a total project cost of \$2,130,173. In Section B.5, pages 11-12, the applicant describes its plans to assure improved energy-efficiency and water conservation. Costs and charges are described by the applicant in Section F, pages 27-31, and in Section R pro forma financial statements. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (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

Bunn Dialysis would be a new facility, thus, it has no historical payor mix. In Section L.7, page 52, the applicant provides the payor mix for DC Franklin County for CY2016. DC Franklin County is the facility that will be contributing ten dialysis stations to develop the proposed facility and from which some of the projected patients will transfer (See Exhibit C-1 for patients' letters of support). The historical payor mix is illustrated as follows:

DC Franklin County Payor Mix CY2016

Payor Type	Percent of Total Patients	Percent of In-Center Patients	Percent of PD Patients
Medicare	21.6%	22.5%	0.0%
Medicaid	10.8%	9.9%	33.3%
Commercial Insurance	9.5%	9.9%	0.0%
Medicare/Commercial	21.6%	19.7%	66.7%
Medicare/Medicaid	33.8%	35.2%	0.0%
VA	2.7%	2.8%	0.0%
Total	100.0%	100.0%	100.0%

As the tables above indicate, 87.8% of DC Franklin County patients had some or all of their services covered by Medicare or Medicaid. The applicant provides a copy of DaVita’s policy on acceptance of patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability in Exhibit L-3.

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**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Franklin	15%	50%	37%	15 %	11%	19%
Nash	16%	52%	48%	18%	11%	18%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table, 2014 Estimate as of December 22, 2015.>

*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., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

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

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

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

The applicant adequately demonstrates that it currently provides access to medically underserved populations. 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 applicants;

C

In Section L.3(e) page 51, the applicant states:

“Bunn 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 51, the applicant states, in reference to any facilities owned by DaVita in the state, that there have been no civil rights equal access complaints filed within the last five years.

The application is conforming to this criterion.

- (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 49, the applicant states that the projected payor mix for Bunn Dialysis is based on sources of payment for its DaVita facilities in Franklin County for the last full operating year, as follows:

²http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

Bunn Dialysis Projected Payor Mix OY2

Payor Type	Percent of Total Patients	Percent of In-Center Patients	Percent of PD Patients
Medicare	21.6%	22.5%	0.0%
Medicaid	10.8%	9.9%	33.3%
Commercial Insurance	9.5%	9.9%	0.0%
Medicare/Commercial	21.6%	19.7%	66.7%
Medicare/Medicaid	33.8%	35.2%	0.0%
VA	2.7%	2.8%	0.0%
Total	100.0%	100.0%	100.0%

The applicant projects that 87.8% of Bunn Dialysis' patients will have some or all of their services covered by Medicare or Medicaid. The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, 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 51, the applicant states that patients will have access to the facility for dialysis services upon referral from a Nephrologist with admitting privileges at the facility. Patients, family, and friends who contact the facility seeking access to services will be referred to *"a qualified nephrologist for evaluation and subsequent admission..."*

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section M.1, page 53, the applicant states that it has offered Bunn Dialysis as a clinical training site for nursing students from Vance-Granville Community College. A copy of a letter sent by the applicant to the college, dated May 1, 2017, is included in Exhibit M-2.

The information provided in Section M.1 and Exhibit M-2 is reasonable and adequately supports a finding of conformity with this criterion.

- (15) Repealed effective July 1, 1987.

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

C

The applicant proposes to develop a new 10-station dialysis facility in Bunn by relocating ten dialysis stations from DC Franklin County. The existing facility and the proposed facility will be located in Franklin County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, Bunn Dialysis will be certified for 10 dialysis stations and DC Franklin County will be certified for 17 dialysis stations.

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

The January 2017 SDR indicates there are two dialysis facility in Franklin County with one of those facilities still under development, as follows:

**Franklin County Dialysis Facilities
 June 30, 2016**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Dialysis Care of Franklin Country	DaVita	77	Louisburg	27	0	71.30%
FMC Tar River	Fresenius Medical Care	Under development – New 10 station facility				

Source: January 2017 SDR

As illustrated above, there are two existing dialysis facilities located in Franklin County with one of those facilities being under development, as of the January 2017 SDR. Of those two facilities, one facility is operated by DaVita and the other facility is operated by

Fresenius. The proposed site for Bunn Dialysis is in the southern part of Franklin County. DC Franklin County operated with a utilization rate over 70. % as of June 30, 2016. The one facility operated by Fresenius had three patients to report as of December 31, 2016 because that is the day the facility was certified.

In Section N.1, page 54, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

“The proposed facility will not have an adverse effect on competition since the patients already being served by DaVita will be transferring their care from one DaVita facility to another DaVita facility, which will be more convenient for the patients who have indicated this in the letters they signed.

... Bunn Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and other [sic] involved in the dialysis process to receive services.”

See also Sections B, C, D, E, F, G, I, K, L, N and O where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- ◆ The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- ◆ The applicant adequately demonstrates that it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- ◆ The applicant demonstrates that it will provide access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

Total Renal Care of North Carolina, LLC, whose parent company is DaVita, Inc., owns and operates 73 facilities in North Carolina as of the July 2017 SDR. In Section O, page 55 and Exhibit O-3, the applicant identifies the three kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period. However, all three facilities are back in compliance with the Medicare conditions of participation. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

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

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

- C- In Section C.1, pages 13-14, the applicant adequately demonstrates that Bunn Dialysis will serve at least 32 in-center patients on 10 stations at the end of the first operating year, which is 3.2 patients per station per week, or a utilization rate of 80% ($32/10 = 3.2$; $3.2/4 = 0.8$). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-NA- The applicant is seeking to develop a new 10-station dialysis facility.

.2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C- In Section C.1, pages 13-15, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.