

ATTACHMENT – REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA – Conditional

NC – Nonconforming

NA = Not Applicable

Decision Date: February 25, 2015

Findings Date: February 25, 2015

Project Analyst: Tanya S. Rupp

Assistant Chief: Martha Frisone

Project ID #: K-10353-14

Facility: Dialysis Care of Franklin County

FID #: 955842

County: Franklin

Applicant: Total Renal Care of North Carolina, LLC

Project: Add four stations to the existing facility for a total of 27 in-center dialysis stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Franklin County (DC Franklin) is currently certified for 23 in-center dialysis stations. In this application, the applicant proposes to add four dialysis stations to the facility, for a total of 27 stations upon completion of this project.

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional dialysis facility or for any additional dialysis stations in Franklin County. However, according to the facility need methodology, an applicant for dialysis stations is eligible to apply for additional dialysis stations if the

utilization rate for the dialysis facility, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. In this application, DC Franklin is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate is 3.21 patients per station, or 80.4%. This utilization rate was calculated based on 74 in-center dialysis patients and 23 certified dialysis stations as of December 31, 2013 (74 patients / 23 stations = 3.21 patients per station). See the following table, from Section III.1, page 23 of the application:

OCTOBER 1 REVIEW-JULY SDR

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/13		80.4%
Certified Stations		23
Pending Stations		
Total Existing and Pending Stations		23
In-Center Patients as of 12/31/13 (July 2014 SDR) (SDR2)		74
In-Center Patients as of 6/30/13 (January 2014 SDR) (SDR1)		67
Step	Description	
	Difference (SDR2 - SDR1)	7
(i)	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/13	0.2090
(ii)	Divide the result of Step (i) by 12	0.0174
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/12 until 12/31/13)	0.2090
(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	89.4627
(v)	Divide the result of Step (iv) by 3.2 patients per station	27.9571
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	4.9571

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.”* As shown in the table above, based on the facility need methodology for dialysis stations, DC Franklin has a need for five additional stations. The applicant proposes to add four new stations and, therefore, the application is consistent with the facility need determination for dialysis stations.

There is one policy in the 2014 SMFP that is applicable to this review: Policy GEN-3. Policy GEN-3, on page 38 of the 2014 SMFP, states:

“A CON 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 (SMFP) 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 CON applicant shall document its plans

for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote safety and quality in Section II, pages 21-22, Section III, page 28, Section V, page 35, Section XI.6(g) pages 62-63, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section V, page 35, Section VI, pages 36-39, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section III, pages 28-29, Section V, page 35, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2014 SMFP. Therefore, the application is consistent with Policy GEN-3

Conclusion

In summary, the applicant adequately demonstrates that its proposal to add four dialysis stations to its existing facility is consistent with the facility need determination in the July 2014 SDR and Policy GEN-3. 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

DC Franklin proposes to add four dialysis stations for a total of 27 stations upon project completion. The applicant currently provides home hemodialysis support and training at DC Franklin and will continue to provide those services following completion of this project. The

July 2014 SDR indicates that, as of December 31, 2013, DC Franklin was certified for 23 in-center dialysis stations and was dialyzing 74 in-center patients.

Population to be Served

In Section III.7, page 25, the applicant identifies the patient population proposed to be served during the first two years of operation following the addition of the four stations, as illustrated in the following table:

COUNTY	OPERATING YEAR 1 (CY 2016)		OPERATING YEAR 2 (CY 2017)		PATIENTS AS % OF TOTAL	
	IN-CTR. PTS.	HOME PTS.	IN-CTR. PTS.	HOME PTS.	OPERATING YEAR 1	OPERATING YEAR 2
Franklin	85	4	91	5	93.6%	94.2%
Vance	2	1	2	1	3.2%	2.9%
Warren	2	1	2	1	3.2%	2.9%
Total	89	6	95	7	100.0%	100.0%

Projected patient origin is based on current patient origin. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In-Center Patients

In Section II.1, pages 14-16 and 17-18, and in Section III.7, pages 25-27, the applicant discusses the need the facility has for the additional in-center dialysis stations. In addition, in Section II.1, pages 16-17, and 19; and Section III.7, pages 27-28, the applicant discusses those patients who are home trained at DC Franklin County. With regard to the in-center patients, the applicant states it calculates growth utilizing the Five Year Average Annual Change Rate (AACR) published in the July 2014 SDR for Franklin County of 7.2%, despite the fact that the facility experienced a 10.4% growth over a six month period, from June 30, 2013 to December 31, 2013.

On April 15, 2013, Total Renal Care of North Carolina, LLC applied for a certificate of need to develop a new dialysis facility in Franklin County by relocating existing stations from existing dialysis facilities, one of which was DC Franklin County. The application also projected that 19 in-center patients would transfer their care to the new facility. That application was denied by the Agency and is currently under appeal. The applicant assumes in this application that no stations will be relocated or patients transferred.

The July 2014 SDR reports that, as of December 31, 2013, DC Franklin County was dialyzing 74 in-center patients on 23 dialysis stations. In Section II.1, page 17, the applicant states:

“We are applying for a four-station expansion based on the Facility Need Methodology. The July 2014 SDR indicates that the five year average annual

change rate for Franklin County was 7.2%. However, with 67 in-center patients as of June 30, 2013 as reported in Table A of the January 2014 SDR and 74 in-center patients as of December 31, 2013 as reported in Table A of the July 2014 SDR, Dialysis Care of Franklin County experienced a growth rate of 10.4% over a six month period from July 1, 2013 to December 31, 2013. This equates to a 20.8% annual growth rate. To be conservative, we have used the 7.2% five year average annual growth rate for the purpose of this CON application. The calculations start with the 70 in-center patients living in Franklin County:

*January 1, 2014-December 31, 2014 – 70 patients X 1.072 = 75.04
January 1, 2015-December 31, 2015 – 75.04 patients X 1.072 = 80.44288*

Based on the patients and stations above, Dialysis Care of Franklin County will have 84 in-center patients on December 31, 2015, the day before the four-station expansion stations are projected to be certified. No growth was calculated for the 4 in-center patients who live outside of Franklin County.”

...

January 1, 2016 – December 31, 2016 – 80 patients x 1.072 = 85.76

January 1, 2017 – December 31, 2017 – 85.76 patients x 1.072 = 91.93472

Operating Year One is projected to begin January 1, 2016 and end on December 31, 2016.

Operating Year Two is projected to begin January 1, 2017 and end on December 31, 2017.

The number of patients ... was rounded down to the nearest whole number. No growth was calculated for the four patients who live outside of Franklin County.

Dialysis Care of Franklin County is projected to have 89 in-center patients at the end of operating year one and 95 in-center patients at the end of operating year two.”

The applicant projects to serve 89 in-center patients on 27 dialysis stations at the end of Operating Year One, which is a utilization rate of 82% [$89 / 27 = 3.296$. $3.296 / 4 = 0.8241$]. In addition, the applicant projects to serve 95 in-center patients on 27 dialysis stations at the end of Operating Year Two, which is a utilization rate of 87% [$95 / 27 = 3.518$. $3.518 / 4 = 0.8796$]. Projected utilization of the 27 in-center dialysis stations at DC Franklin County is based on reasonable and adequately supported assumptions.

Home Trained Patients

In Section II.1, page 19; and Section III.7, pages 27-28, the applicant provides the assumptions and methodology used to project the number of home trained patients. As of December 31, 2013, DC Franklin had six home trained patients. Four lived in Franklin County, one lived in Vance County, and one lived in Warren County. The applicant projects the number of home trained patients during the first two Operating Years, as follows:

“The growth is based on the 4 home-trained patients living in Franklin County:

January 1, 2014 - December 31, 2014 - 4 patients X 1.072 = 4.288

January 1, 2015 - December 31, 2015 - 4.288 patients X 1.072 = 4.596736

Home-trained patient growth projections for patients receiving training and support at Dialysis Care of Franklin County but living in Vance and Warren Counties were not calculated. Therefore, as of December 31, 2015 there will be a total of 6.59 home-trained patients (4.5 Franklin County patients and 2 patients living outside of Franklin County), the day before the projected certification of the four expansion stations.

The period of the growth begins with January 1, 2016 forward to December 31, 2017. The following are the in-center [sic] patient projections using a 7.2% for the purpose of this application.

January 1, 2016 – December 31, 2016 - 4.5 patients X 1.072 = 4.824

January 1, 2017 – December 31, 2017 – 4.824 patients X 1.072 = 5.171328

Operating Year One is projected to begin January 1, 2016 and end on December 31, 2016

Operating Year Two is projected to begin January 1, 2017 and end on December 31, 2017

The number of patients stated above was rounded down to the nearest whole number. No growth was calculated for the 2 home-trained patients who live outside of Franklin County.

Dialysis Care of Franklin County is projected to have 6 home-trained patients at the end of operating year one and 7 home-trained patients at the end of operating year two.”

Projected utilization is based on reasonable and adequately supported assumptions.

The applicant adequately demonstrates the need the population proposed to be served has for the addition of four dialysis stations at DC Franklin County.

Access to Services

In Section VI, page 36, the applicant states,

“DC of Franklin County, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”

In Section VI.1(c), page 37, the applicant projects that 89.9% of its in-center patients will be covered by Medicare or Medicaid. With regard to its home trained patients, the applicant projects that 85.7% will be covered by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, 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 adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the dialysis proposed services. 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.

NA

- (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 III.9, pages 28-29, the applicant describes the alternatives it considered prior to submitting this application. On page 28, the applicant states:

“There were only two alternatives of meeting the needs of the proposed project considered [sic]. The first was to do nothing. This alternative was dismissed since the patient population continues to grow. The second was to apply for a four-station expansion based on the facility need methodology. We chose the second alternative in order to help meet the growing demand for dialysis services at DC of Franklin County.”

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

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

- 1. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Franklin County shall materially comply with all representations made in the certificate of need application.**
 - 2. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Franklin County shall add no more than four dialysis stations to its existing facility, for a facility total of no more than 27 stations upon project completion, which shall include any home hemodialysis training or isolation stations.**
 - 3. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Franklin County shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations, which shall include any home hemodialysis training or isolation stations.**
 - 4. Prior to issuance of the certificate of need, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Franklin County shall submit documentation of an invitation to a professional training program in Franklin or Wake counties to use the facility for training students.**
 - 5. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Franklin County 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.

In Section VIII.1, page 45, the applicant states that the total capital cost of the project is projected to be \$279,240 which includes \$180,000 in construction costs, \$62,500 for dialysis machines, \$18,605 for water treatment equipment, \$1,135 for dialysis chairs, \$6,000 for televisions, and \$11,000 for patient computer systems.

In Section IX.3, page 49, the applicant projects no working capital (start-up and initial operating expenses) associated with the proposed project, since the facility is currently operational and the application is for the addition of four stations.

In Section VIII.2, page 46, the applicant states that the project will be funded from cash reserves; and on page 47, the applicant states DaVita Healthcare Partners Inc., the ultimate parent company of Total Renal Care of North Carolina, LLC, will provide the cash reserves for the development of this project.

In Exhibit 18, the applicant provides a September 10, 2014 letter from the Chief Accounting Officer of DaVita Healthcare Partners, which states in part:

“I am the Chief Accounting Officer of DaVita Healthcare Partners, Inc., the parent and 100% owner of DVA Healthcare Renal Care, Inc. I also serve as the Chief Accounting Officer of Total Renal Care, Inc., which owns 85% of the ownership interests in Total Renal Care of North Carolina, LLC.

We are submitting a Certificate of Need application to expand our Dialysis Care of Franklin County by four ESRD dialysis stations. The project calls for a capital expenditure of \$279,240. This letter will confirm that DaVita HealthCare Partners Inc. has committed cash reserves in the total sum of \$279,240 for the project capital expenditure. DaVita HealthCare Partners 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.”

In Exhibit 19, the applicant provides the audited financial statements for DaVita Healthcare Partners, Inc. for the fiscal year ended December 31, 2013. As of December 31, 2013, DaVita Healthcare Partners, Inc. had \$946,249,000 in cash and cash equivalents, \$17,098,877,000 in total assets and \$4,605,541,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In Section X.1, page 51, the applicant provides the allowable charges per treatment for each payment source, as illustrated below in the table.

DIALYSIS CARE OF FRANKLIN COUNTY	
PAYOR	CHARGE /TREATMENT
Medicare	\$239.02
Medicaid	\$143.00
Medicare/Medicaid	\$239.02

Commercial Insurance	\$1,275.00
VA	\$193.00
Medicare/Commercial	\$239.02

The applicant projects revenues in Section X.2, page 52, and operating expenses in Section X.4, pages 55-56, as illustrated in the following table:

DIALYSIS CARE OF FRANKLIN COUNTY		
	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$4,044,258	\$4,326,358
Total Operating Costs	\$3,453,319	\$3,635,617
Net Profit	\$590,939	\$690,741

The applicant projects that revenues will exceed operating expenses in each of the two operating years following project completion. The assumptions used in preparation of the pro formas, including the number of projected treatments are reasonable and adequately supported. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges. 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

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Franklin County, whose parent company is DaVita HealthCare Partners, Inc., proposes to add four dialysis stations to the existing facility, for a total of 27 in-center dialysis stations upon project completion. Currently, DC Franklin County is the only dialysis facility in Franklin County. A certificate of need application was conditionally approved for Bio-Medical Applications of North Carolina, Inc. to develop a new 10-station dialysis facility in Louisburg, approximately one mile from DC Franklin County. That decision is currently under appeal.

The applicant adequately demonstrates the need to add four stations to the existing facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved certified dialysis stations 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

In Section VII.1, page 40, the applicant provides projected staffing during Operating Year Two, as illustrated in the following table:

FULL TIME EQUIVALENT (FTE) POSITIONS	
RN	4.0
HTRN	0.5
PCT	11.0
Bio-Med Tech	0.5
Admin.	1.0
Dietician	1.0
Social Worker	0.5
Unit Secretary	1.0
Reuse	1.0
Total FTEs	20.5

The applicant proposes to employ a total of 20.5 FTE positions. The applicant proposes to add two FTE PCT positions as a result of the project. In Section V.4, page 34, the applicant identifies the Medical Director for Dialysis Care of Franklin County as Dr. Tariq Abo-Kamil. In Exhibit 13, the applicant provides a September 10, 2014 letter from Dr. Abo-Kamil indicating the doctor's willingness to continue to serve as Medical Director of the facility.

The applicant adequately documents the availability of resources, including health manpower and management personnel, for 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 Sections V.1 and V.2, pages 32 - 33, the applicant lists the providers of the necessary ancillary and support services that will serve the patients dialyzing at Dialysis Care of Franklin County. Maria Parham, WakeMed and Franklin Regional Medical Center provide emergency services, acute hemodialysis services, diagnostic and evaluation services, X-ray services, blood bank services, and vascular surgery services. The other services are provided by the

individual providers listed in the table provided on page 32. In Section V.1, page 33, the applicant states laboratory services will be provided by Maria Parham, Duke University Health System, and WakeMed. In addition, the applicant provides supporting documentation regarding ancillary services in Exhibit 10. The applicant discusses coordination with the existing health care system in Sections V.2 – V.6, pages 32 - 35. The applicant provides supporting documentation of coordination with the existing health care system in Exhibit 12. The information provided in those sections and exhibits is reasonable and credible and supports a finding of conformity with 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

- (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.

NA

- (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 VI.1, page 35, the applicant states

“Dialysis Care of Franklin County, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”

The applicant’s dialysis policies, procedures, and guidelines with regard to accepting patients for dialysis care are provided in Exhibit 14.

The table below illustrates the historical payor mix for the facility, as reported by the applicant on page 36.

DC FRANKLIN HISTORICAL PAYOR MIX		
PAYOR SOURCE	IN-CENTER	HOME TRAINED
Medicare	18.8%	0.0%
Medicaid	7.2%	14.3%
Medicare/Medicaid	34.9%	28.6%
Commercial Insurance	7.2%	14.3%
VA	2.9%	0.0%
Medicare/Commercial	29.0%	42.8%
Total	100.0%	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Franklin County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Franklin County	18%	7%	20%

Statewide	17%	7%	20%
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*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99*).¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender do not include information on the number of elderly, handicapped, minorities or women utilizing health services.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis”*² (p. 216)

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which show that 65.4% were white, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p.218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.” (p. 216).

The *2013 USRDS Annual Data Report* provides 2011 ESRD spending by payor, as follows:

¹<http://www.esrdnetwork6.org/utlils/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

² www.usrds.org/adr.aspx

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
Total	\$49.2	100.0%

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2013		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
Gender		
Female	6,845	44.5%
Male	8,544	55.5%
Race		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.³

The applicant demonstrates that medically underserved populations currently have adequate access to services available at Dialysis Care of Franklin County. 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;

³<http://www.esrdnetwork6.org/utlils/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

C

In Section VI.1(f), page 37, the applicant states, “*Dialysis Care of Franklin County has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons...*” In Section VI.6(a), page 39, the applicant states “*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 VI.1(c), page 37, the applicant provides the projected payor mix for the proposed dialysis services at DC Franklin. The applicant projects no change from the current payor mix. The applicant projects 89.9% of the in-center patients who will receive treatments at DC Franklin and 85.7% of the home-trained patients will have some or all of the services paid for by Medicare or Medicaid.

In Section VI.2, page 38, the applicant states the facility is currently designed and constructed to accommodate handicapped persons, and currently serves a number of “*severely handicapped*” persons. The applicant further states that the facility will not change as a result of this project.

The applicant demonstrates that the elderly and medically underserved populations will continue to have adequate access to the proposed dialysis services at DC Franklin County. 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 VI.5, pages 38 - 39, the applicant describes the range of means by which patients will have access to the proposed dialysis services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity with 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.

CA

In Section V.3, page 33, the applicant states Dialysis Care of Franklin County has existing clinical training agreements with Education Corporation of America. Exhibit 12 contains a copy of an existing agreement between DaVita and Education Corporation of America to provide opportunities for nursing students to use Dialysis Care of Franklin County as a clinical training site. However, the applicant does not adequately demonstrate that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. Therefore, the application is conforming to this criterion subject to Condition #4 in Criterion (4).

- (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

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Franklin County proposes to add four dialysis stations to its existing facility, for a total of 27 in-center dialysis stations at Dialysis Care of Franklin County upon project completion.

The July 2014 SDR shows that, at the time the application was submitted, there was one operational dialysis facility located in Franklin County. Bio-Medical Applications of North Carolina, Inc. was approved in 2013 to develop a new 10-station dialysis facility, also in Louisburg. That decision was appealed, and thus there is one facility currently operating in Franklin County. In this application, the applicant is applying to add four dialysis stations to DC Franklin County based on the Facility Need methodology and the number of in-center patients it proposes to serve. The July 2014 SDR reports that as of December 31, 2013, DC Franklin County was operating at 80.4% capacity, with 74 in-center patients dialyzing on 23 stations [$74 / 23 = 3.22$; $3.22 / 4 = 0.8044$]. The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility, pursuant to 10A NCAC 14C .2203(b).

In Section V.7, page 35, the applicant states that the proposed facility expansion is not intended to be a competitive venture; rather, a response to the needs of the facility and its patients. Total Renal Care of North Carolina, LLC is currently the only provider of dialysis services in Franklin County.

See also Sections II, III, V, VI and VII, in which the applicant discusses the cost-effectiveness, quality and access to the proposed services.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that adding four dialysis stations to DC Franklin County will have a positive impact on cost-effectiveness, quality and access to the proposed service because:

- The applicant adequately demonstrates the need to add four dialysis stations to the existing facility, for a total of 27 certified in-center dialysis stations upon completion of the proposed project. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to DC Franklin County dialysis patients;
- The applicant adequately demonstrates it will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 (pages 32 - 35), and VII (pages 40 - 42), and referenced exhibits is reasonable and credible and demonstrates the provision of quality care.
- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations in need of dialysis services in Franklin County. In Section VI.1, page 36, the applicant states:

“Dialysis Care of Franklin County, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.” [sic]

In Section VI, pages 36 - 39, the applicant explains that medically underserved populations will continue to have adequate access to DC Franklin County dialysis services following the addition of the stations as proposed in this application.

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.

DC Franklin is an existing facility. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation during the eighteen months immediately preceding the date of this decision. 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

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

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

- (a) *An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:*
- (1) *Utilization rates;*
-C- On pages 26 and 30, the applicant states the utilization rate at DC Franklin was 80.4% as of December 31, 2013.
- (2) *Mortality rates;*
-C- In Section IV.2, page 30, the applicant states the mortality rates were 15.0%, 14.3% and 12.3% in 2011, 2012 and 2013, respectively.
- (3) *The number of patients that are home trained and the number of patients on home dialysis;*
-C- In Section IV.3, page 30, the applicant states DC Franklin had six patients who are home trained at the time the application was filed.
- (4) *The number of transplants performed or referred;*

- C- In Section IV.4, page 30, the applicant states DC Franklin referred 13 patients for transplant evaluation in 2013. The applicant states one transplant was actually performed in 2013.
- (5) *The number of patients currently on the transplant waiting list;*
- C- In Section IV.5, page 31, the applicant states DC Franklin has five patients currently on the transplant waiting list.
- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- In Section IV.6, page 31, the applicant states that there were 226 total hospital admissions in CY 2013, 42 of which were dialysis related and 184 that were non-dialysis related.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- In Section IV.7, page 31, the applicant states that there were two patients with AIDS dialyzing at DC Franklin as of December 31, 2013. There were no other patients with any other infectious diseases dialyzing at the facility.
- (b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*
 - (1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*
 - NA- DC Franklin is an existing facility.
 - (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
 - (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) *composition of the assessment/evaluation team at the transplant center,*
 - (C) *method for periodic re-evaluation,*
 - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
 - (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*

- NA- DC Franklin is an existing facility.
- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- DC Franklin is an existing facility.
- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- See Exhibit 8 for a copy of the policies and procedures for back-up electrical service in the event of a power outage for DC Franklin.
- (5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- DC Franklin is an existing facility.
- (6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- In Section XI.6(g), page 62, the applicant states, *“Dialysis Care of Franklin County has and will continue to operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment and other relevant health safety requirements.”*
- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- In Section II.1, pages 14-17, and Section III.7, pages 25-28, the applicant provides the methodology and assumptions used to project patient origin as shown in the following table:

COUNTY	OPERATING YEAR 1		OPERATING YEAR 2		COUNTY PATIENTS AS PERCENT OF TOTAL	
	IN-CTR.	HOME	IN-CTR.	HOME	YEAR 1	YEAR 2
Franklin	85	4	91	5	93.6%	94.2%
Vance	2	1	2	1	3.2%	2.9%
Warren	2	1	2	1	3.2%	2.9%
Total	89	6	95	7	100.0%	100.0%

The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- DC Franklin is an existing facility.
- (9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*
- C- In Section II.1, page 14, the applicant states, *“Total Renal Care of North Carolina d/b/a Dialysis Care of Franklin County will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such 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- DC Franklin does not propose 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- DC Franklin projects 3.2 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 15 - 19, and Section III.7, pages 25 - 28. The discussion regarding analysis of need 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- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 15 - 19, and Section III.7, pages 25 - 28. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

10A NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

- (1) *diagnostic and evaluation services;*
-C- In Section V.1, page 32, the applicant states Maria Parham, WakeMed and Franklin Regional Medical Center will provide diagnostic and evaluation services.
- (2) *maintenance dialysis;*
-C- In Section V.1, page 32, the applicant states patients will receive maintenance dialysis services at the facility.
- (3) *accessible self-care training;*
-C- In Section II.1, pages 16 – 17, the applicant states DC Franklin trains those patients who are candidates for home training.
- (4) *accessible follow-up program for support of patients dialyzing at home;*
-C- In Section II.1, pages 16 – 17, the applicant states DC Franklin County provides services for those patients who are home trained.
- (5) *x-ray services;*
-C- In Section V.1, page 32, the applicant states x-ray services will be provided by Maria Parham Medical Center, WakeMed and Franklin Regional Medical Center.
- (6) *laboratory services;*
-C- In Section V.1, page 33, the applicant states laboratory services will be provided by Maria Parham Medical Center, Duke University Medical Center and WakeMed.
- (7) *blood bank services;*
-C- In Section V.1, page 31, the applicant states blood bank services will be provided by Maria Parham Medical Center, WakeMed and Franklin Regional Medical Center.
- (8) *emergency care;*
-C- In Section V.1, page 32, the applicant states emergency care services will be provided by Maria Parham Medical Center, WakeMed and Franklin Regional Medical Center.
- (9) *acute dialysis in an acute care setting;*
-C- In Section V.1, page 32, the applicant states acute dialysis services will be provided by Maria Parham Medical Center and WakeMed.
- (10) *vascular surgery for dialysis treatment patients;*
-C- In Section V.1, page 32, the applicant states vascular surgery services will be provided by Maria Parham Medical Center and WakeMed.
- (11) *transplantation services;*
-C- In Section V.1, page 32, the applicant states transplantation services will be provided by Carolinas Medical Center.

- (12) vocational rehabilitation counseling and services; and
-C- In Section V.1, page 32, the applicant states vocational rehabilitation counseling and services will be provided by the North Carolina Division of Vocational Rehabilitation Services.
- (13) *transportation.*
-C- In Section V.1, page 33, the applicant states transportation services will be provided by KARTS.

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

- (a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.*
-C- In Section VII.1, page 40, the applicant states that all staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.
- (b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
-C- In Exhibit 17 the applicant provides a copy of the applicant's training program outline for dialysis nurses and technicians.