

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: September 25, 2013

PROJECT ANALYST: Kim Randolph  
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: K-10126-13/ Total Renal Care of North Carolina, LLC d/b/a Youngsville Dialysis/ Develop a new 10-station dialysis facility in Youngsville by relocating eight dialysis stations from Dialysis Care of Franklin County (Franklin County) and two dialysis stations from Wake Forest Dialysis Center (Wake County)/ Franklin County

### 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.

NC

ESRD dialysis station need determinations are published semiannually, in the January and July North Carolina Semiannual Dialysis Report (SDR), by the State Health Coordinating Council and the Medical Facilities Planning Branch, Division of Health Service Regulation, Department of Health and Human Services, pursuant to Chapter 14 of the 2013 North Carolina State Medical Facilities Plan (2013 SMFP). The January 2013 SDR is the applicable SDR for applications submitted in 2013 prior to July 1, 2013. The July 2013 SDR is the applicable SDR for applications submitted in 2013 after July 1, 2013.

The applicant, Total Renal Care of North Carolina, LLC (TRCNC) d/b/a Youngsville Dialysis, whose parent company is DaVita Healthcare Partners Inc., filed this application on April 15, 2013 for the review cycle beginning May 1, 2013, based in part on a 10-station deficit projected in the January 2013 SDR for Franklin County. The applicant proposes to develop a new 10-station dialysis facility in Youngsville (Franklin County), located at Youngsville Crossing, Lot 9, by relocating 8 existing dialysis stations from Dialysis Care of Franklin County (Franklin County) and 2 existing dialysis stations from Wake Forest

Dialysis Center (Wake County). The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

According to Chapter 3 of the 2013 SMFP, *“The Certificate of Need Section shall determine the appropriate review category or categories in which an application shall be submitted pursuant to 10A NCAC 14C .0202.”* Rule 10A NCAC 14C .0202(e) states *“Proposals requiring review shall be reviewed according to the categories and schedule set forth in the duly adopted State Medical Facilities Plan in effect at the time the scheduled review period commences, as contained in this Subchapter.”* Category I proposals include *“relocation within the same county of existing licensed nursing facility beds, existing licensed adult care home beds, or existing certified dialysis stations; ... and projects not included in Categories A through H or Categories J through M.”* Category D proposals include *“relocation of existing certified dialysis stations to another county pursuant to Policy ESRD-2.”* TRCNC’s application falls into both Category I and Category D. Chapter 3 of the 2013 SMFP states on page 17, *“For proposals which include more than one category, an applicant must contact the Certificate of Need Section prior to submittal of the application for a determination regarding the appropriate review category or categories and the applicable review period in which the proposal must be submitted.”*

The CON Section determined that TRCNC’s application was a Category I because 8 of the 10 stations to be relocated (80%) would be relocated within Franklin County while only 2 of the 10 stations (20%) would be relocated from a contiguous county. The application deadline for the TRCNC Category I proposal, located in Health Service Area IV, was April 15, 2013 with a CON review period starting May 1, 2013.

Previously, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Tar River filed a Category D proposal on March 15, 2013, for the review cycle beginning April 1, 2013, also based on the 10-station deficit projected in the January 2013 SDR for Franklin County. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Tar River proposed to develop a new 10-station dialysis facility in Louisburg (Franklin County) by relocating 10 existing dialysis stations from Wake County to Franklin County.

Shortly after the application deadline for each review cycle, the CON Section publishes a list on its website of all applications received for that review cycle. It appears that TRCNC was aware of the BMA application before it submitted its application. On May 13, 2013, the CON Section received a letter from TRCNC’s attorney, requesting that the CON Section review TRCNC’s application competitively with the BMA application submitted for an earlier review cycle.

Pursuant to 10A NCAC 14C .0202(f), *“Applications are competitive if they, in whole or in part, are for the same or similar services and the agency determines that the approval of one or more of the applications may result in the denial of another application reviewed in the same review period.”* (Emphasis added) Because the TRCNC application is a Category I, filed in the May 1 Review Cycle, and the FMC Tar River application is a Category D, filed

in the April 1 Review Cycle, the applications are not competitive pursuant to 10A NCAC 14C. 0202(f).

The January 2013 SDR and the 2013 SMFP provide a county need and facility need methodology for determining the need for new dialysis stations. When the appropriate SDR indicates a dialysis station deficit of 10 or greater in a county and the utilization of each dialysis facility in that county is 80 percent or greater, a county need is generated, otherwise the county need determination is zero. When the county need determination is zero and the facility's reported utilization, in the applicable SDR, is 3.2 patients per station or greater, the facility can apply for additional stations at the existing facility. The January 2013 SDR, *Table B: ESRD Dialysis Station Need Determination by Planning Area* projects a 10-station deficit in Franklin County. However, the utilization of dialysis stations in the only existing dialysis facility in Franklin County (the applicant's facility, Dialysis Care of Franklin County (DC of Franklin County)) is less than 80% and the patients per station are less than 3.2 patients per station, therefore the county need determination is zero.

The county and facility need methodologies in the January 2013 SDR and the 2013 SMFP are not applicable to this review.

However, *Policy ESRD-2: Relocation of Dialysis Stations* is applicable to this review. Policy ESRD-2 states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of Need applicants proposing to relocate dialysis stations to contiguous counties shall:*

- (1) Demonstrate that the proposal shall not result in a 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*
- (2) Demonstrate that the proposal shall not result in a 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 relocate eight existing dialysis stations within Franklin County and two existing dialysis stations from Wake County to Franklin County. Wake and Franklin counties are contiguous to each other. Relocating eight dialysis stations within Franklin County will not change the Franklin County inventory; however relocating two dialysis stations from Wake County to Franklin County will decrease the Wake County dialysis station inventory by two stations and increase the Franklin County inventory by two stations. Table B in the January 2013 SDR, shows a 19-station surplus in Wake County and a 10-station deficit in Franklin County, the county into which the applicant proposes to relocate the stations.

Since Franklin County is showing a deficit of 10-stations, relocating 2 dialysis stations from Wake County would not result in a surplus in the number of dialysis stations in Franklin County, unless a previously submitted application was approved which would reduce or eliminate the deficit. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Tar River had previously submitted a Category D application in the April 1 Review Cycle, which if approved, would increase the dialysis station inventory in Franklin County by 10 stations, effectively eliminating the 10-station deficit in Franklin County shown in the January 2013 SDR. Since Wake County is showing a surplus of 19-stations, relocating 2 dialysis stations from Wake County would not result in a deficit in the number of dialysis stations in Wake County, even if FMC Tar River is approved.

On August 27, 2013, the CON Section approved the FMC Tar River proposal to establish a new 10-station dialysis facility in Franklin County, by relocating 10 stations from Wake County to Franklin County, effectively eliminating the 10-station dialysis station deficit in Franklin County in the January 2013 SDR. Thus, approval of TRCNC's proposal to relocate two dialysis stations from Wake County to Franklin County would result in a surplus of two dialysis stations in Franklin County. Therefore, this application is not consistent with Policy ESRD-2. Consequently, this application is not conforming with 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

TRCNC currently operates the only dialysis facility in Franklin County, DC of Franklin County, a 23-station facility located in Louisburg. The January 2013 SDR shows that DC of Franklin County was operating at 75% utilization, with 69 in-center patients dialyzing on 23 stations [ $69 / 23 = 3.00$ ;  $3.00 / 4 = 75\%$ ]. The applicant also operates a 25-station dialysis facility located in Wake Forest, Wake Forest Dialysis Center. The January 2013 SDR shows that Wake Forest Dialysis Center was operating at 102.50% utilization, with 41 in-center patients dialyzing on 10 stations [ $41 / 10 = 4.10$ ;  $4.10 / 4 = 102.5\%$ ]. The January 2013 SDR also indicates that Wake Forest Dialysis Center had five additional dialysis stations pending approval. The CON Section issued a CON for those five additional dialysis stations on March 19, 2013 (Project I.D.# J-10038-12). In Section III.3, page 22, the applicant states the five additional dialysis stations have been certified. When considering the five additional dialysis stations, Wake Forest Dialysis Center is operating at 68% utilization, with 41 in-center patients dialyzing at 15 stations [ $41 / 15 = 2.73$ ;  $2.73 / 4 = 68\%$ ].

The applicant proposes to establish a new 10-station dialysis facility, Youngsville Dialysis, in Franklin County by relocating eight existing dialysis stations from DC of Franklin County (Franklin County) and two existing dialysis stations from Wake Forest Dialysis Center (Wake County). In Section II.1, page 12, the applicant projects that a total of 30 existing in-center TRCNC patients will transfer from DC of Franklin County and Wake Forest Dialysis Center to the Youngsville facility. The applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations.

Population to be Served

In Section III.7, page 25, the applicant provides the projected patient origin for the patients it proposes to serve for the first two years of operation, as illustrated in the table below.

County	Operating Year 1 CY 2015		Operating Year 2 CY 2016		County Patients as a Percent of Total	
	In-Center	Home	In-Center	Home	Year 1	Year 2
Franklin	30	7	32	8	88.0%	89.0%
Granville	2	0	2	0	4.8%	4.4%
Vance	0	1	0	1	2.4%	2.2%
Wake	0	1	0	1	2.4%	2.2%
Warren	0	1	0	1	2.4%	2.2%
<b>Total</b>	32	10	34	11	100.0%	100.0%

The above patient origin is based on the following methodology and assumptions provided by the applicant in Section II, pages 13-15 and Section III.7, pages 25-27.

- “• *Dialysis Care of Franklin County had 69 in-center patients as of 6/30/2012 for a utilization rate of 75%.*
- *Dialysis Care of Franklin County does not have the capacity to add additional dialysis stations to the facility and [cannot] does not have the property to expand the building.*
- *Many of the patients dialyzing at Dialysis Care of Franklin County live in Franklinton and Youngsville.*
- *The development of a second facility to be located in the southwestern corner of Franklin County would provide patients who are admitted to Dialysis Care of Franklin County, living in Franklinton and Youngsville, easier access to dialysis services.*
- *Wake Forest Dialysis Center had 41 in-center patients and ten dialysis stations as of 6/30/2012 for a utilization rate of 102.5%.*

- *Wake Forest Dialysis Center had a certificate of need application under review to add five stations to the existing facility that was submitted on September 17, 2012.*
- *Taking the five stations into consideration, Wake Forest Dialysis Center had a utilization rate of 68% based on fifteen in-center stations (ten certified and five under review at the time the January 2013 SDR was published).*
- *Wake Forest Dialysis Center had several patients who live in Youngsville and Franklinton in Franklin County who drive across county lines to receive their dialysis treatments three times a week.*
- *The patients who drive across county lines to receive their dialysis treatments would have access to in-county transportation services at the proposed Youngsville Dialysis.*
- *The patients who drive across county lines would save time and gas money by having a dialysis center in Youngsville, which would be closer to their homes and much more convenient.*
- *The patients who drive across county lines would have a less congested and safer drive to a dialysis facility in Youngsville.*
- *Franklin County patients receiving their dialysis treatments at the Wake Forest Dialysis Center would prefer to receive services in their home county which will be more convenient and closer to their homes.”*
- Operating Year One is projected to begin January 1, 2015 and end on December 31, 2015.
- Operating Year Two is projected to begin January 1, 2016 and end on December 31, 2016.
- Utilization rates for the end of the first and second operating years were calculated using the Franklin County five-year Average Annual Change Rate (AACR) of 7.7% reported in the January 2013 SDR.

In Section II, pages 12-15, the applicant discusses the projected population for Youngsville Dialysis and states that 30 patients currently receiving in-center hemodialysis at DC of Franklin County and Wake Forest Dialysis Center indicated they would consider transferring their care because the proposed facility is closer and more convenient to where they live. In Section III, pages 21-26, the applicant projects 19 current in-center patients and 7 home dialysis patients, trained in peritoneal dialysis, will transfer from DC of Franklin County and 11 current in-center patients will transfer from Wake Forest Dialysis Center to the proposed Youngsville facility.

Exhibit 16 contains 28 in-center dialysis patient letters of support. In Section III.3, page 20, the applicant states two additional patients have verbally indicated their support for the new facility. After the proposed relocation of stations and transfer of patients, the applicant projects Youngsville Dialysis will begin the first year of operation with 30 in-center ESRD patients, consisting of residents of Franklin and Granville counties. The applicant adequately identifies the population to be served.

Demonstration of Need

The applicant proposes to relocate 10 certified dialysis stations from existing facilities in Franklin and Wake counties to develop a new facility in Franklin County. In Section II.1, page 13, the applicant states that a second facility, located in the southwestern corner of Franklin County, will provide easier access to dialysis services for current patients living in Franklinton and Youngsville. The applicant states that DC of Franklin County does not have the space to add additional dialysis stations to its facility. In Section II.2, page 17, the applicant states TRCNC is also proposing to relocate home training and support in peritoneal dialysis to Youngsville Dialysis, since there is not adequate space at DC of Franklin County to continue offering home training in peritoneal dialysis.

In Section III.7, pages 25-27, the applicant projects Youngsville Dialysis' patient volumes for the first two years of operation, based on a starting census of 30 in-center dialysis patients as shown below.

TRCNC begins with the 30* current in-center patients from DC of Franklin County and Wake Forest Dialysis Center who indicated an interest in transferring to Youngsville Dialysis on January 1, 2015.	30 in-center patients
TRCNC projects this patient population forward for 12 months to December 31, 2015, using the Franklin County five-year AACR of 7.7%.	$(30.00 \times 1.077) = 32.31$
TRCNC projects the 2015 Youngsville Dialysis patient population forward for 12 months to December 31, 2016, using the Franklin County five-year AACR of 7.7%.	$(32.31 \times 1.077) = 34.80$

\* Note: The county of residence for the initial 30 in-center patients is not discussed or clearly explained in the methodology or assumptions as including both Granville and Franklin County patients. Granville County patient origin is reflected only in the chart on page 25 of the application.

The Performance Standards for dialysis facilities, as promulgated in 10A NCAC 14C .2203(a), requires an applicant to “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...” As shown on the chart above, the applicant adequately demonstrates that it will serve a total of 32 patients dialyzing at 10 in-center dialysis stations at the end of the first operating year, which is 3.2 patients per station per week, or a utilization rate of 80% of capacity [32 / 10 = 3.2; 3.2 / 4 = 80%]. Projected utilization is based on reasonable, credible and supported assumptions. Therefore, the applicant adequately demonstrated that the proposed Franklin County facility would serve 3.2 patients per station per week as required by 10A NCAC 14C .2203(a).

Access to Services

In Section VI, page 38, the applicant states

*“Youngsville Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.*

...

*Youngsville Dialysis will not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”*

The applicant projects that 87.6% of its patients will be covered by Medicare and Medicaid. The applicant adequately demonstrates adequate access for the medically underserved to its services.

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed project, and demonstrates all residents of the service area, and in particular, underserved groups, are likely to have access to the services proposed. 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.

C

The applicant proposes to establish a new dialysis facility in Youngsville by relocating existing dialysis stations from two different facilities located in Franklin and Wake counties. In Section III, pages 23-27, the applicant describes the impact of the proposed relocation of stations from DC of Franklin County and Wake Forest Dialysis Center.

**DC of Franklin County (Franklin County)**

In Section III.6, page 23, the applicant states DC of Franklin County has 23 certified dialysis stations. According to the January 2013 SDR, the facility was operating at 75% capacity with 69 in-center patients utilizing the 23 certified dialysis stations.

The applicant states that relocating 8 dialysis stations and transferring 19 in-center patients from DC of Franklin County to Youngsville Dialysis will result in DC of Franklin County having 15 certified stations [23 – 8 = 15] and 50 in-center patients [69 – 19 = 50] which does

not include patient growth from June 30, 2012 until January 1, 2015, Youngsville Dialysis' projected certification date. To account for potential growth, the applicant states it used the Franklin County five-year AACR of 7.7% as shown in the table below.

**DC of Franklin County**

TRCNC begins with the 69 ESRD in-center dialysis patient population listed in the January 2013 SDR, as of June 30, 2012.	69 in-center patients
TRCNC projects this patient population forward for six months from July 1, 2012 to December 31, 2012, using the Franklin County five-year AACR of 7.7%.	$69 \times 1.0385 = 71.6565$
TRCNC projects the 2012 patient population forward for 12 months to December 31, 2013, using the Franklin County five-year AACR of 7.7%.	$71.6565 \times 1.077 = 77.1741$
TRCNC projects the 2013 patient population forward for 12 months to December 31, 2014, using the Franklin County five-year AACR of 7.7%.	$77.1741 \times 1.077 = 83.1165$
TRCNC deducts the 19 patients who have indicated an interest in transferring to Youngsville Dialysis as of January 1, 2015.	$83 - 19 = 64$

On page 21, the applicant projects DC of Franklin County will operate at 106% [107%] capacity with 64 in-center patients dialyzing on 15 stations as of January 1, 2015. On page 24, the applicant states

*“...Dialysis Care of Franklin County will be applying for additional in-center stations as the patient census grows during the development of the Youngsville facility. When the eight stations are transferred to Youngsville Dialysis, the additional stations at DC Franklin will be certified the same day the ten transferring stations are certified at Youngsville Dialysis. Therefore, based on the plan to apply for additional station [sic] once DC Franklin reaches or exceeds 80% utilization during the development of the Youngsville facility, the needs of the patients remaining at the DC Franklin County will be adequately met. Additional Certificate of Need application(s) will be submitted based on facility need at DC Franklin until the facility reaches full capacity of 23 stations.”*

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

**Wake Forest Dialysis Center (Wake County)**

In Section III.6, page 24, the applicant states Wake Forest Dialysis Center has 15 certified dialysis stations. According to the January 2013 SDR, the facility was operating at 68% capacity with 41 in-center patients utilizing the 15 certified dialysis stations.

The applicant states that relocating 2 dialysis stations and 11 in-center patients from Wake Forest Dialysis Center to Youngsville Dialysis will result in Wake Forest Dialysis Center having 13 certified stations [ $15 - 2 = 13$ ] and 30 in-center patients [ $41 - 11 = 30$ ] which does

not include patient growth from June 30, 2012 until January 1, 2015, Youngsville Dialysis' projected certification date. To account for potential growth, the applicant uses the Wake County five-year AACR of 4.2% as shown in the table below.

**Wake Forest Dialysis Center**

TRCNC begins with the 41 ESRD in-center dialysis patient population listed in the January 2013 SDR, as of June 30, 2012.	41 in-center patients
TRCNC projects the patient population forward for six months from July 1, 2012 to December 31, 2012, using the Wake County five-year AACR of 4.2%.	$41 \times 1.021 = 41.861$
TRCNC projects the 2012 patient population forward for 12 months to December 31, 2013, using the Wake County five-year AACR of 4.2%.	$41.861 \times 1.042 = 43.6192$
TRCNC projects the 2013 patient population forward for 12 months to December 31, 2014, using the Wake County five-year AACR of 4.2%.	$43.6192 \times 1.042 = 45.4512$
TRCNC deducts the 11 patients who have indicated an interest in transferring to Youngsville Dialysis, as of January 1, 2015.	$45 - 11 = 34$

On page 25, the applicant projects Wake Forest Dialysis Center will operate at 65% capacity with 34 in-center patients dialyzing at 13 stations as of January 1, 2015.

Therefore, the applicant demonstrates that the needs of the population presently served at Wake Forest Dialysis Center will continue to be adequately met following the proposed relocation of two stations from Wake Forest Dialysis Center to Youngsville Dialysis and that access for medically underserved groups will not be negatively impacted.

The applicant proposes to develop a new 10-station dialysis facility in Youngsville, Franklin County, by relocating existing stations from two dialysis facilities located in Franklin and Wake counties. The applicant adequately demonstrates that the two facilities from which dialysis stations would be relocated would have sufficient capacity following the relocation of stations to the proposed Youngsville facility. Thus the applicant adequately demonstrates that the needs of the population presently served will be adequately met by the proposed relocation of dialysis stations. 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.

NC

In Section III.9, pages 27-28, the applicant discusses the alternatives considered prior to the submission of its application, which include:

- 1) Maintain the Status Quo – The applicant states this alternative is not as effective because the utilization rate of both DC of Franklin County and Wake Forest Dialysis Center will continue to increase. Patients want to travel to a facility that will reduce

their travel time and be more convenient. A total of 30 in-center patients have expressed an interest in considering a transfer to the facility in Youngsville.

- 2) Create a new 10-station dialysis center in Youngsville – The applicant states that creating a new 10-station dialysis center in Youngsville, by relocating 8 certified dialysis stations from DC of Franklin County and 2 certified dialysis stations from Wake Forest Dialysis Center, is the most effective alternative because southwestern Franklin County has more need for a dialysis center than any other area of the county.

At the time this application was submitted, it appears the applicant was aware that another provider, Bio-Medical Applications of North Carolina Inc. d/b/a FMC Tar River, had already filed an application on March 15, 2013 for the review cycle beginning April 1, 2013, proposing to develop a new 10-station dialysis facility in Franklin County by relocating 10 stations from Wake County. The applicant does not address the approval or disapproval of the FMC Tar River application in this application. Since the FMC Tar River application was approved on August 27, 2013, there is no longer a deficit of stations in Franklin County and approval of this application would result in a surplus of dialysis stations in Franklin County.

Furthermore, this application is not conforming to all other applicable statutory review criteria, and thus, is not approvable. See Criteria (1), (6), and (18a). A project that cannot be approved cannot be an effective alternative.

In summary, the applicant does not adequately demonstrate that this proposal is the least costly or more effective alternative to meet the stated need. Therefore, the application is nonconforming to this criterion and cannot be approved.

- (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

In Section VIII, pages 47-48, the applicant projects a capital cost of \$1,260,489. The capital costs include construction costs of \$808,000 and miscellaneous project costs of \$452,489 which include in part, dialysis machines for \$131,700, water treatment equipment for \$86,000, televisions for \$18,000, and dialysis chairs for \$9,900. The applicant states it will fund the project from the cash reserves of DaVita Healthcare Partners, Inc. In Section IX.3, page 51, the applicant states there will be start-up expenses of \$200,419 which include inventory of consumable supplies for \$50,000 and staff training for \$150,419. In Section IX.2, page 51, the applicant states there will be initial operating expenses of \$847,035 for a total working capital requirement of \$1,047,454.

Exhibit 21 contains a letter dated April 12, 2013, from the Chief Accounting Officer of DaVita Healthcare Partners, Inc., which states

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

*We are submitting a Certificate of Need application to develop a ten-station End Stage Renal Disease hemodialysis facility in Youngsville in Franklin County. The facility will also operate a peritoneal dialysis training and support program. I am writing this letter as Chief Accounting Officer of DaVita, to confirm DaVita’s commitment of \$1,260,489 for the capital expenditure associated with this project; a commitment of \$200,419, for its start up expenses; and a further commitment of \$847,035 in working capital. Note that this working capital commitment is sufficient to cover all of the projected operating expenses for a period of six months of operation of this new facility.*

*DaVita has committed cash reserves in the total sum of \$2,307,943, for the capital costs, start-up costs and working capital for this project.”*

In Exhibit 22, the applicant provides the audited financial statements for DaVita Healthcare Partners Inc. for the fiscal years ending December 31, 2012 and 2011. As of December 31, 2012, DaVita Healthcare Partners Inc. had \$533,748,000 in cash and cash equivalents, \$16,018,596,000 in total assets and \$3,928,048,000 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.

In Section X.1, page 53, the applicant projects the following charges per treatment for each payment source as shown below.

<b>Payment Source</b>	<b>In-Center Charge Per Treatment</b>
Medicare	\$240
Medicaid	\$143
Medicare/Medicaid	\$240
Commercial Insurance	\$1,442
VA	\$193
Medicare/Commercial	\$240

Based on the calculations presented in Section X.3, page 54, the facility reimbursement per treatment for each payment source is shown below.

Payment Source	Reimbursement Per Treatment
Medicare	\$192
Medicaid	\$143
Medicare/Medicaid	\$240
Commercial Insurance	\$1,442
VA	\$193
Medicare/Commercial	\$240

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.

In Sections X.2-X.4, pages 53-55, the applicant reports projected revenues and expenses for the first two operating years. The applicant projects revenues will exceed operating expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

	<b>Operating Year 1 (OY1) 01/01/2015 - 12/31/2015</b>	<b>Operating Year 2 (OY2) 01/01/2016 - 12/31/2016</b>
Total Projected Net Revenue	\$1,830,687	\$1,942,088
Total Projected Operating Costs	\$1,694,070	\$1,774,223
Projected Net Profit	\$136,617	\$167,865

Source: Application pages 53-55.

In Section X, page 55, the applicant provides projected staffing and salaries. In Section VII, page 43, the applicant states the facility is in compliance with the requirements of 42 C.F.R. Section 494 (formerly 405.2100). Staffing by shift is provided on page 46. The applicant projects adequate staffing to provide dialysis treatments for the number of patients projected.

Operating costs and revenues are based on reasonable assumptions including projected utilization. See Section X, pages 53-56, of the application for the applicant's assumptions. See Criterion (3) for discussion regarding utilization which is incorporated hereby as if set forth fully herein.

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

The applicant proposes to develop a new 10-station dialysis facility in Youngsville by relocating existing stations from two TRCNC facilities located in Franklin and Wake counties. The Performance Standards for dialysis facilities, as promulgated in 10A NCAC 14C .2203(a), requires an applicant to “*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...*” The applicant is not applying for additional stations due to a facility or county need methodology; but is applying to relocate existing dialysis stations from two facilities, based in part on a projected 10-station deficit in Franklin County listed in the January 2013 SDR.

TRCNC operates the only existing dialysis facility in Franklin County, a 23-station facility located in Louisburg, DC of Franklin County. At the time this application was submitted, it appears the applicant was aware that Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Tar River had submitted an application, which if approved, would increase the dialysis station inventory in Franklin County by 10 stations, effectively eliminating the 10-station deficit in Franklin County in the January 2013 SDR. The applicant does not discuss the approval or disapproval of the FMC Tar River application.

On August 27, 2013, the FMC Tar River application was approved. Thus, there is no longer a deficit of stations in Franklin County. Consequently, the applicant does not adequately demonstrate that relocating two stations from Wake County to Franklin County will not result in the unnecessary duplication of existing and approved in-center dialysis stations in Franklin County. Therefore, the application is nonconforming 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 43, the applicant provides the current and projected number of full-time equivalent (FTE) positions as shown in the table below.

Youngsville Dialysis  
 Project I.D. #K-10126-13  
 Page 15

POSITION	CURRENT # OF FTEs	PROJECTED # OF NEW FTEs	TOTAL # OF FTEs
RN	0.0	1.5	1.5
PDRN	0.0	1.0	1.0
Patient Care Tech (PCT)	0.0	4.5	4.5
Bio-Med Tech	0.0	0.3	0.3
Admin.	0.0	1.0	1.0
Dietician	0.0	0.3	0.3
Social Worker	0.0	0.3	0.3
Unit Secretary	0.0	1.0	1.0
Reuse Tech	0.0	0.5	0.5
<b>Total</b>	<b>0.0</b>	<b>10.4</b>	<b>10.4</b>

Note: The Medical Director is a contract position, not an FTE of the facility.

As shown in the table above, the applicant proposes to employ a total of 10.4 full-time equivalent (FTE) positions to staff Youngsville Dialysis upon completion of the proposed project.

The following table shows the projected number of direct care staff for each shift offered in the facility.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6 am to 11 am	3	3	3	3	3	3
Afternoon	11 am to 4 pm	3	3	3	3	3	3
Evening	N/A	0	0	0	0	0	0

Source: Application page 46.

In Section V.4, page 35, the applicant states that Dr. Tariq Abo-Kamil will serve as medical director of the facility and is a board-certified nephrologist. Exhibit 15 contains a letter that confirms his commitment to serve as the medical director. In Section VII.4, pages 44-45, the applicant states it will transfer some employees from DC of Franklin County and Wake County Dialysis Center to staff the Youngsville facility. Any positions not filled by transfer will be filled in advance of the facility opening and training will be provided at both the Franklin County and Wake County facilities. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed 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.

In Section V, pages 33-34, the applicant lists the providers of the necessary ancillary and support services to be provided for the proposed facility. The applicant indicates that Maria Parham, WakeMed, and Franklin Regional Medical Center will provide emergency services, diagnostic evaluation services, X-ray services, and blood bank services. In addition, Maria Parham and WakeMed will provide acute hemodialysis services and vascular surgery services. The other services provided by individual providers are listed on page 33. The applicant provides supporting documentation in Exhibits 8 and 9. The applicant discusses coordination with the existing health care system in Section V, pages 34-36. The applicant provides supporting documentation in Exhibits 14-16. The information provided in Section V and the listed 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

NA

- (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 XI.6, page 60, Section I.10, page 3 and Exhibit 26 of the application, the applicant states an unrelated developer will construct the shell space for the proposed 6,500 square foot dialysis facility in Youngsville which the applicant will up-fit and lease. The applicant states each dialysis station will have 152 square feet per station. In Section XI.6, page 61 of the application, the applicant states the facility will be constructed with energy-efficient glass, mechanically operated patient access doors and energy-efficient heating and cooling. The applicant states that the facility will be located in an area with city water and sewer and discusses its procedures for modifying the water quality and providing for power outages. Exhibits 10-11 contain supporting documentation and Exhibit 26 contains a line drawing of the floor plan for the facility.

Cost and charges are described by the applicant in Section X of the application, pages 53-56. See discussion in Criterion (5) regarding costs and charges which is incorporated hereby as if set forth fully herein.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, 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

In Section VI.1, pages 38-41, the applicant discusses TRCNC’s history of providing dialysis services to the underserved populations of North Carolina. Exhibit 17 contains the applicant’s dialysis policies, procedures, and guidelines. On page 38, the applicant states

*“Youngsville Dialysis, by policy, will make dialysis services available to all residents in its service area without qualification. We will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.”*

The applicant reports that 87.6% of the patients who received treatment at DC of Franklin County and 73.7% of patients who received treatment at Wake Forest Dialysis Center had some or all of the services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payor mix of each facility.

<b>DC of Franklin County</b>	
<b>Payor Source</b>	<b>Percentage</b>
Medicare	11.3%
Medicaid	7.5%
Medicare/Medicaid	36.3%
Commercial Insurance	6.2%
VA	6.2%
Medicare/Commercial	32.5%
<b>Total</b>	<b>100.0%</b>

<b>Wake Forest Dialysis Center</b>	
<b>Payor Source</b>	<b>Percentage</b>
Medicare	15.8%
Medicaid	5.3%
Medicare/Medicaid	15.8%
Commercial Insurance	22.8%
VA	3.5%
Medicare/Commercial	36.8%
<b>Total</b>	<b>100.0%</b>

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 and Wake counties and statewide.

	<b>2011 Total # of Medicaid Eligibles as % of Total</b>	<b>2011 Total # of Medicaid Eligibles Age 21 and older</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G.</b>

	Population *	as % of Total Population *	Sheps Center) *
Franklin County	18%	7.4%	19.7%
Wake County	10%	3.3%	18.4%
Statewide	17%	6.7%	19.7%

\* 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 dialysis services offered by TRCNC. In fact, according to the Southeastern Kidney Council’s ESRD Network 6 2011 Annual Report, only 5.8% of all newly-diagnosed ESRD patients (incident ESRD patients) in North Carolina’s Network 6 were under the age of 35.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available 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, minorities or women utilizing health services. Furthermore, OSBM’s website does not include information on the number of handicapped persons.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of the Medicare-covered patients had employer group health plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states

*“Although the ESRD population is less than 1% of the entire U.S. population, it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. ...*

*Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”*

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report provides these national statistics for FY 2010: *“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy.”* Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states

*“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”*

The report provides the following 2010 ESRD spending by payor.

<b>ESRD Spending by Payor</b>		
<b>Payor Source</b>	<b>Spending in Billions</b>	<b>% of Total Spending</b>
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340.

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, gender, and race as shown below.

<b>Number and Percent of Dialysis Patients by Age, Gender, and Race*</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
<b>Gender</b>		
Female	4,237	45.4%
Male	5,105	54.7%
<b>Race</b>		
African-American	5,096	54.6%
White	4,027	43.1%
Other	219	2.3%
<b>Total</b>	<b>9,342</b>	<b>100.0%</b>

\* Source: SKC Network 6, which includes North Carolina, South Carolina, and Georgia.

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant’s existing services and is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access

by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.1, page 41 of the application, the applicant states

*“Youngsville Dialysis will have 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. Youngsville Dialysis will have no obligation under the Hill Burton Act.”*

In Section VI.6, page 42, the applicant states, *“There have been no civil rights equal access complaints filed within the last five years.”* Therefore, 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, page 39, the applicant provides the projected payor mix as follows:

Youngsville Dialysis Projected Patient Payor Mix	
Payor Source	Percentage
Medicare	12.5%
Medicaid	6.3%
Medicare/Medicaid	37.4%
Commercial Insurance	6.3%
VA	5.0%
Medicare/Commercial	32.5%
<b>Total</b>	100.0%

As shown in the table above, the applicant projects 88.7% of in-center patients will be Medicare or Medicare/Medicaid beneficiaries.

In Section VI.1, page 40, the applicant states *“...it has been DaVita’s practice in North Carolina to accept patients in need of dialysis treatment **first**, and assist them with insurance and billing issues later.”*

In Section VI.2, page 41, the applicant states “*Youngsville Dialysis will satisfy all state requirements and local building codes to allow equal access for handicapped patients.*”

The applicant demonstrates that the elderly and 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 VI.5, page 41, and Exhibit 17, the applicant describes the range of means by which patients will have access to the proposed 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.

C

In Section V.3, page 35, the applicant states “*Youngsville Dialysis will be offered as a clinical learning site for nursing students at the local community college.*” Exhibit 14 contains a letter from DaVita’s Facility Administrator at DC of Franklin County to the President of Vance-Granville Community College offering Youngsville Dialysis as a clinical learning site. The information provided in Section V.3 is reasonable and credible and 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.

NC

The applicant proposes to develop a new 10-station dialysis facility in Youngsville (Franklin County) by relocating existing stations from two TRCNC facilities located in Franklin and Wake counties. The applicant operates the only existing dialysis facility in Franklin County, a 23-station facility located in Louisburg, DC of Franklin County.

In Section V.7, page 36, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality, and access to the proposed services. The applicant states

*“The development of this facility will have no impact on the other outpatient dialysis facility, DC of Franklin County. Total Renal Care of North Carolina, LLC operates DC of Franklin County.*

...

*The development of Youngsville Dialysis is a proposal to relocate stations and a number of the patients receiving their dialysis treatments at DC of Franklin County and Wake Forest Dialysis Center. The growth projections for DC of Franklin County and Wake Forest Dialysis Center are based on that existing patient population. Therefore, our projections for the proposed Youngsville Dialysis facility do not depend on any change in existing referral patterns. Our goal is to locate an in-center ESRD facility closer to where many of our current patients live, and closer to an area of Pender [sic] County where there is a large concentration of patients.*

*For these reasons, we do not believe that this new facility will have an impact on any Fresenius facility located in contiguous counties. Youngsville 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....”*

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality, and access. However, the applicant does not adequately demonstrate that the proposal will have a positive impact on the cost-effectiveness of dialysis services in Franklin County. This determination is based on the information in the application and the following analysis:

- The January 2013 SDR, *Table B: ESRD Dialysis Station Need Determination by Planning Area* projects a 10-station deficit in Franklin County;
- On April 15, 2013, TRCNC filed this Category I application proposing to develop a new 10-station dialysis facility in Franklin County by relocating two stations from

Wake County to Franklin County and by relocating eight stations within Franklin County. The review cycle began May 1, 2013;

- On March 15, 2013, one month earlier, Bio-Medical Applications of North Carolina Inc. d/b/a FMC Tar River had filed a Category D application proposed to develop a new 10-station dialysis facility in Franklin County by relocating 10 stations from Wake County to Franklin County. The review cycle began April 1, 2013;
- FMC Tar River's application was approved on August 27, 2013, effectively eliminating the 10-station deficit in Franklin County in the January 2013 SDR;
- Approval of TRCNC's proposal would create a surplus of two dialysis stations in Franklin County;
- TRCNC does not address the approval or disapproval of the FMC Tar River application in its application;
- Approval of only a portion of TRCNC's application (i.e., the relocation of the eight stations within Franklin County) would not be consistent with the Performance Standards for dialysis facilities, as promulgated in 10A NCAC 14C .2203(a), which requires an applicant to "*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...*".
- TRCNC does not adequately demonstrate how any enhanced competition will have a positive impact on the cost effectiveness of dialysis services in Franklin County.

Consequently, the application is nonconforming 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

The applicant proposes to relocate dialysis stations from two of its existing facilities, DC of Franklin County and Wake Forest Dialysis Center, to a new facility in Franklin County. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, those facilities have operated in compliance with all Medicare Conditions of Participation within the 18 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, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The application is conforming to all applicable criteria, which are discussed below.

**10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT**

*(a) An applicant that proposes to increase stations in an existing certified facility or relocate stations must provide the following information:*

*.2202(a)(1) Utilization rates;*

- C- In Section II.1, page 10, the applicant states the utilization rate is reported in the January 2013 SDR and Section IV. In Section IV, pages 29 and 31, the applicant discusses a facility in Jacksonville rather than the facilities in Wake and Franklin counties. However, the January 2013 SDR, a publicly available document prepared by the Division of Health Service Regulation at the direction of the State Health Coordinating Council, includes the utilization rates for DC of Franklin County and Wake Forest Dialysis Center.

*.2202(a)(2) Mortality rates;*

- C- In Section IV.2, pages 29 and 31, the applicant reports the 2010, 2011, and 2012 facility mortality rates for DC of Franklin County and Wake Forest Dialysis Center.

*.2202(a)(3) The number of patients that are home-trained and the number of patients on home dialysis;*

- C- In Section IV.3, page 29, the applicant states that DC of Franklin County had 12 peritoneal dialysis patients and zero home hemodialysis patients as of December 31, 2012. Wake Forest Dialysis Center had seven home-trained patients as of December 31, 2012.

.2202(a)(4) *The number of transplants performed or referred;*

- C- In Section IV.4, page 29, the applicant states DC of Franklin County referred seven patients for transplant evaluation in 2012 and one patient received a transplant in 2012. In Section IV.4, page 31, the applicant states Wake County Dialysis Center referred eighteen patients for transplant evaluation in 2012 and three patients received a transplant in 2012.

.2202(a)(5) *The number of patients currently on the transplant waiting list;*

- C- In Section IV.5, page 30, the applicant states that DC of Franklin County has two patients on the transplant waiting list. In Section IV.5, page 31, the applicant states that Wake County Dialysis Center has seven patients on the transplant waiting list.

.2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

- C- In Section IV.6, page 30, for DC of Franklin County, the applicant reports a total of 73 hospital admissions in 2012; 4.1% were dialysis-related admissions and 95.9% were non-dialysis related admissions. In Section IV.6, page 32, for Wake Forest Dialysis Center, the applicant reports a total of 60 hospital admissions in 2012; 13.3% were dialysis-related admissions and 86.7% were non-dialysis related admissions.

.2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*

- C- In Section IV.7, page 30, for DC of Franklin County, the applicant reports that in 2012 there were three patients with AIDS and no patients with Hepatitis B. Zero patients converted to infectious status in 2012. In Section IV.7, page 32, for Wake County Dialysis Center, there were zero patients with an infectious disease, and zero patients converted to infectious status in 2012.

*(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:*

.2202(b)(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 (Replaced with 42 CFR Part 494).*

- C- Exhibit 8 contains a letter of intent from Maria Parham Medical Center to enter into a Patient Transfer Agreement with the applicant, which describes the services that the hospital will provide to patients of Youngsville Dialysis.

- .2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a 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.*
- C- Exhibit 9 contains a letter of intent from Carolinas Medical Center to enter into a Transplant Agreement with the applicant, which includes the information required by this rule.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- In Section XI.6, page 61, the applicant states that city water and standing power service will be available for Youngsville Dialysis' proposed sites. Exhibit 11 contains a copy of DaVita's water quality policy. Exhibit 24 contains letters of confirmation from providers regarding the availability of city water and power.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- Exhibit 10 contains a copy of DaVita's Hemodialysis Policies, Procedures, and Guidelines for Termination of Dialysis in an Emergency, which includes written policies and procedures for back up of electrical service in the event of a power outage.
- .2202(b)(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.*
- C- Exhibit 24 contains a written commitment by the builder to pursue acquiring the site and building a building, including the intent to lease the building to the applicant upon completion. Exhibit 24 also contains specification of a secondary site and statements that the primary and secondary sites are available.

- .2202(b)(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- See Sections II.1, page 10; VII.2, pages 43-44; and XI.6, pages 61-62.
- .2202(b)(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 III.3, pages 20-22, the applicant provides the assumptions and methodology it used to project patient origin. See Criterion (3) for further discussion on patient origin which is incorporated hereby as if set forth fully herein.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- C- In Section III.8, page 27, the applicant states that 100% of patients will travel less than 30 miles one way for dialysis treatment.
- .2202(b)(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 for such services.*
- C- In Section II.1, page 12, the applicant states, “*Total Renal Care of North Carolina, LLC d/b/a Youngsville Dialysis 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.*”

## **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 II.1, pages 12-15, the applicant adequately demonstrates it will serve a total of 32 in-center patients on 10 dialysis stations at the end of the first operating year, which is 3.2 patients per station per week [32 / 10 = 3.2], or a utilization rate of 80%.
- .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.*
- N/A- The applicant is not 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.

- .2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II.1, pages 13-15, the applicant provides the assumptions and methodology used to project utilization of the facility. The applicant projects an annual increase in its current Franklin County patient utilization using the Franklin County five-year AACR of 7.7% from the January 2013 SDR. The applicant also makes assumptions about patients who have expressed an interest in transferring to the proposed facility.

## **10 NCAC 14C .2204 SCOPE OF SERVICES**

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

- .2204(1) Diagnostic and evaluation services;*
- C- See Section V.1, page 33 and Exhibit 8. The applicant states Maria Parham, WakeMed and Franklin Regional Medical Center will provide diagnostic and evaluation services.
- .2204(2) Maintenance dialysis;*
- C- See Section V.1, page 33. The applicant states it will provide maintenance dialysis.
- .2204(3) Accessible self-care training;*
- C- See Section V.1, page 33. The applicant states self-care training will be provided by the applicant through DC of Franklin County.
- .2204(4) Accessible follow-up program for support of patients dialyzing at home;*
- C- See Section V.1, page 34. The applicant states it provides follow-up programs for support of patients dialyzing at home. The applicant states home-trained patients are monitored by its Quality Management team.
- .2204(5) X-ray services;*
- C- See Section V.1, page 33 and Exhibit 8. The applicant states Maria Parham, WakeMed and Franklin Regional Medical Center will provide X-ray services.
- .2204(6) Laboratory services;*
- C- See Section V.1, page 33. The applicant states Dialysis Laboratories will provide laboratory services.
- .2204(7) Blood bank services;*
- C- See Section V.1, page 33. The applicant states Maria Parham, WakeMed and Franklin Regional Medical Center will provide blood bank services.

- .2204(8) *Emergency care;*
  - C- See Section V.1, page 33. The applicant states Maria Parham, WakeMed and Franklin Regional Medical Center will provide emergency care.
  
- .2204(9) *Acute dialysis in an acute care setting;*
  - C- See Section V.1, page 33. The applicant states Maria Parham and WakeMed will provide acute dialysis in an acute care setting.
  
- .2204(10) *Vascular surgery for dialysis treatment patients*
  - C- See Section V.1, page 33. The applicant states Maria Parham and WakeMed will provide vascular surgery for dialysis treatment patients.
  
- .2204(11) *Transplantation services;*
  - C- See Section V.1, page 33 and Exhibit 9. The applicant states Carolinas Medical Center will provide transplantation services.
  
- .2204(12) *Vocational rehabilitation counseling and services; and*
  - C- See Section V.1, page 33. The applicant states the North Carolina Department of Vocational Rehabilitation will provide vocational rehabilitation counseling and services.
  
- .2204(13) *Transportation*
  - C- See Section V.1, page 33. The applicant states KARTS will provide transportation.

## **10 NCAC 14C .2205 STAFFING AND STAFF TRAINING**

- .2205(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 (Replaced with 42 CFR Part 494).*
  - C- In Section VII, pages 43-44, the applicant provides the proposed staffing and states Youngsville Dialysis complies with all staffing requirements set forth in 42 C.F.R., Part 494 (formerly 405.2100). See Criterion (7) for further discussion on staffing which is incorporated hereby as if set forth fully herein.

*.2205(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- See Section VII.3, page 44 and Exhibit 20.