

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: July 11, 2014  
PROJECT ANALYST: Fatimah Wilson  
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: N-10283-14 Total Renal Care of North Carolina, LLC d/b/a Maxton Dialysis / Relocate St. Pauls Dialysis Center, a 10 station dialysis facility, to Maxton and rename it Maxton Dialysis / Robeson 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.

### C

Total Renal Care of North Carolina, LLC (TRC) proposes to relocate St. Pauls Dialysis Center from St. Pauls, to Maxton, within Robeson County. The facility is currently certified for 10-stations and provides in-center dialysis and peritoneal dialysis training and support. The applicant states that upon relocation of the facility, the facility will be renamed Maxton Dialysis. The applicant proposes to relocate the facility from 564 W. McLean Street, St. Pauls to 102 Pine Street, Maxton, which is approximately 36.7 miles according to MapQuest.

According to the January 2014 Semiannual Dialysis Report (SDR), Table A page 17, St. Pauls Dialysis Center was operating at 1.6 patients per station as of June 30, 2013, with a utilization rate of 40% ( $16 / 10 = 1.6$ ;  $1.6 / 4 = 0.40$ , or 40%). The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Neither of the two need methodologies in the 2014 State Medical Facilities Plan (SMFP) is applicable to the review. In addition, Policy GEN-3 is not applicable to this review since there is no identified need for additional dialysis stations in Robeson County. In fact, the January 2014 SDR indicates that Robeson County has a surplus of eight stations.

However, SMFP Policy ESRD-2 is applicable to this review. Policy ESRD-2, found on page 41 of the 2014 SMFP 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:*

- (A) 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*
- (B) 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 St. Pauls Dialysis Center from St. Pauls to establish an End Stage Renal Disease (ESRD) facility in Maxton, also in Robeson County. Since the proposed relocation of stations is within the host county, there is no change in the dialysis station inventory in Robeson County. Therefore the application is conforming to Policy ESRD-2, and 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.

NC

TRC proposes to relocate St. Pauls Dialysis Center from St. Pauls in northeastern Robeson County, to Maxton, in southwestern Robeson County. The facility is currently certified for 10-stations and provides in-center dialysis and peritoneal dialysis training and support. The applicant states that upon relocation of the facility, St. Pauls Dialysis Center will be renamed Maxton Dialysis. The applicant does not propose to increase the number of dialysis stations in the facility, and does not propose to acquire additional dialysis stations that would result in an increase in the inventory of dialysis stations in Robeson County.

#### Population to be Served

In Section IV.1, page 29, the applicant identifies its current in-center patient population as of June 30, 2013 as shown in the table below.

<b>St. Pauls Dialysis Center</b>
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COUNTY OF RESIDENCE	NUMBER OF IN-CENTER PATIENTS
Robeson	9
Cumberland	5
Hoke	1
Bladen	1
<b>Total</b>	<b>16</b>

In Section III.7, page 23, the applicant projects patient origin for Maxton Dialysis for the first two project years following the relocation of St. Pauls Dialysis Center, as shown in the table below.

**Projected Number of In-Center & Home  
 Dialysis Patients  
 First Two Operating Years**

COUNTY	OPERATING YEAR 1 (CY 2016)		OPERATING YEAR 2 (CY 2017)		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients	Year 1	Year 2
Robeson	17	4	18	5	55.3%	56.1%
Scotland	14	2	14	3	42.1%	41.5%
Marlboro, SC	1	0	1	0	2.6%	2.4%
<b>TOTAL</b>	<b>32</b>	<b>6</b>	<b>33</b>	<b>8</b>	<b>100%</b>	<b>100%</b>

As shown above, the applicant is proposing a new service area upon relocation of the facility. St. Pauls Dialysis is currently located in northeastern Robeson County. The existing facility is in close proximity to Bladen, Cumberland and Hoke Counties. Maxton Dialysis would be located approximately 36.7 miles from the existing site of St. Pauls Dialysis Center, in southwestern Robeson County. Maxton Dialysis would be in close proximity to Scotland County. Therefore, the proposed service area change is reasonable, given the distance between the facility's current location and the site the applicant has chosen for the relocation of the facility.

On page 23, the applicant states that Maxton Dialysis will provide in-center dialysis treatment to 17 Robeson County residents, 14 Scotland County residents and one Marlboro County resident. In Exhibit 16, the applicant provided 27 support letters (21 in-center and six home training) from patients who state they will consider transferring their dialysis care from the dialysis facility where they are now receiving treatments. Of the 21 in-center patients, eight are residents of Robeson County, 12 are residents of Scotland County and one is a resident of Marlboro, SC, as shown in the following table.

Patient's County	# of	# of	Total # of	Percent Total
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of Residence	In-Center Patients	Home Patients	Patients	
Robeson	8	6	14	51.9%
Scotland	12	0	12	44.4%
Marlboro, SC	1	0	1	3.7%
Total	21	6	27	100.0%

As shown in the tables above, the applicant did not base projected patient origin on the support letters provided in Exhibit 16. The applicant states they will be providing in-center dialysis treatment to 32 in-center patients by the end of operating year one, however, based on the support letters provided, the applicant only demonstrates that they will be providing in-center dialysis treatment to 21 in-center patients. Therefore, the applicant's projected patient origin does not correlate to the patient origin demonstrated by the support letters provided.

The applicant states in Section III.8, page 27 that all of the patients who will utilize Maxton Dialysis will live within a 30-mile radius of the facility. However, the applicant does not provide any documentation regarding where the proposed patients actually live. The patients who provided support letters do not indicate that the proposed Maxton Dialysis facility in Maxton will be closer or more convenient for them than their current facility.

The applicant does not adequately identify the population it proposes to serve. See discussion in the need analysis below regarding the reasonableness of the projections.

### Need Analysis

The January 2014 SDR indicates that there are six dialysis facilities located in Robeson County, two of which are located in St. Pauls, as shown in the table below.

Facility	City	# of Certified Stations	# of In-Center Patients	Utilization by Percent	Patients per Station
St. Pauls Dialysis	St. Pauls	10	16	40.0%	1.60
FMC St. Pauls	St. Pauls	13	44	84.62%	3.38
BMA of Red Springs	Red Springs	14	40	71.43%	2.86
FMC Robeson County	Fairmont	23	66	71.74%	2.87
FMC Pembroke	Pembroke	13	49	94.23%	3.77
FMC Lumberton	Lumberton	30	104	86.67%	3.47

Source: Table A, page 17 of the January 2014 SDR as of June 30, 2013

As shown above, St. Pauls Dialysis Center was dialyzing 16 patients on 10 in-center dialysis stations as of June 30, 2013, for a utilization rate of 1.6 patients per station [ $16 / 10 = 1.6$ ;  $1.6 / 4 = 0.4$ , or 40%]. In Section III.9, page 27, the applicant states the facility has been operating only three days a week since the FMC St. Pauls facility was certified,

and therefore, without a change in location, the facility will eventually have to close, due to low utilization.

The following table is of historical utilization for the St. Pauls Dialysis Center facility as indicated in SDR data from July 2007 to January 2009.

SDR	# of Certified Stations	# of In-Center Patients	Utilization by Percent	Patients per Station
July 2007	10	0	0.0%	0.00
January 2008	10	17	43.0%	1.70
July 2008	10	18	45.0%	1.80
January 2009	10	16	40.0%	1.60

As shown in the table above, St. Pauls Dialysis Center has been experiencing low utilization since certification of the facility in 2007. The low utilization did not begin in 2009 when the FMC St. Pauls facility was certified. St. Pauls Dialysis' utilization has been historically low since certification of the facility. In Section III.9, page 27, the applicant states that St. Pauls Dialysis Center will have to close due to a lack of patients if the facility remains at the current location. Therefore, the applicant is proposing a relocation of the entire facility.

In Section III.4, pages 21-22, the applicant describes the need to relocate the facility to Maxton. The applicant states,

*"...TRC has a relationship with Dr. Jonathan Nestor who lives and practices in Scotland County. Dr. Nestor serves as the Medical Director for a dialysis facility operated by TRC that is located just over the state line in South Carolina. Dr. Nestor has indicated that there are several patients living in the Maxton area who would transfer their care to a facility operated by TRC in Maxton. ..."*

As stated above, the need to relocate the facility to Maxton is based on the premise that Dr. Nestor has patients living in the Maxton area who would prefer a TRC facility in Maxton. The support letters do not indicate the area of Robeson or Scotland County in which the patients live, nor that the Maxton Dialysis facility would be closer to the patients' homes. In Section II.1, page 15 and Section III.7, page 25, the applicant states,

*"TRC assumes that all ESRD patients prefer to dialyze at a facility that is convenient and close to their place of residence. Specifically, ESRD patients residing in [sic] Maxton area will want to dialyze at a dialysis facility nearer to their homes."*

The applicant states that it is more convenient for a dialysis patient to dialyze closer to home, however, it was not indicated anywhere in the application how the Maxton Dialysis facility would be a closer or more convenient option for dialysis care, as opposed to the facility where the patient is currently dialyzing. An indication that the Maxton facility would be

closer to the patients' home, while not required, would have supported the need to relocate the facility to the Maxton area.

In Sections II.1, pages 14-16 and Section III.7, pages 23-26, the applicant provides the assumptions it used to project patient utilization.

- *“TRC assumes that there is a significant number [sic] in-center ESRD dialysis patients lining [sic] in the Maxton area that will transfer their care to Maxton Dialysis upon opening of the relocated facility.*
- *TRC assumes that all ESRD patients prefer to dialyze at a facility that is convenient and close to their place of residence. Specifically, ESRD patients residing in Maxton area will want to dialyze at a dialysis facility nearer to their homes.*
- *The patient population living in Robeson and Scotland Counties will be projected forward using the current Five Year Average Annual Change Rate of 2.6% as published in the January 2014 SDR.*
- *TRC assumes that the percentage of patients dialyzing on home therapies on June 30, 2015 will be the same as the percentage published in the July 2013 SDR. The July 2013 [sic] indicates that as of December 31, 2012, 7.8% [sic] of the dialysis patients in Robeson County were home dialysis patients.*
- *TRC assumes that the St. Pauls Dialysis Center operated by Total Renal Care of North Carolina, LLC will continue to experience a decline in the patient population at the St. Pauls facility.*

*Letters of support from patients indicating a willingness to consider transferring to a new facility are strong evidence of patient support and commitment. However, there is no requirement, rule or criteria that indicate a letter of support must be submitted for each patient that is proposed to transfer to the facility upon certification.*

*The period of growth begins with January 1, 2016, which is the projected date of certification for Maxton Dialysis. The following are the in-center patient projections using the 2.6% Average Annual Change Rate for the Past Five Years as indicated on the first page of Table B of the January 2014 Semiannual Dialysis Report. TRC proposes to have 32 in-center patients on the waiting list to begin treatment at Maxton Dialysis based on letters of support and patients who have not signed letters of support, but indicated to Dr. Nestor that they would transfer their care to Maxton Dialysis upon certification.*

*January 1, 2016-December 31, 2016—32 in-center patients X 1.026 = 32.832*

*January 1, 2017-December 31, 2017— 32.832 in-center patients X 1.026 =*

33.685632

*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*

*Home Training in Peritoneal Dialysis*

*Dr. Nestor has indicated that there are ten peritoneal dialysis patients that will consider transferring their care and support to Maxton Dialysis upon certification of the facility. To be conservative, TRC projects that six peritoneal dialysis patients will transfer to Maxton Dialysis at opening and two additional peritoneal dialysis patients will be admitted to Maxton Dialysis during operating year two. These are conservative estimates based on the growth of the peritoneal dialysis patient population by DaVita owned facilities in North Carolina and the commitment to the modality by Dr. Nestor.”*

On page 26, the applicant states:

**“NOTE: The number of in-center hemodialysis patients for operating year 1 and 2 will be used to determine the number of treatments, operating revenue and operating expenses.”**

In Section III.9, page 27, the applicant states,

*“A study was conducted to identify an alternate location in Robeson County for the TRC St. Pauls Dialysis Center. The study indicated that a ten-station facility located in Maxton would have a significant number of patients transfer their care to a TRC facility in Maxton.”*

The applicant states above that a study was done to identify where in Robeson County the St. Pauls Dialysis facility needed to be relocated. However, the applicant did not provide any further explanation of the study that was done, nor demonstrate anywhere in the application how the Maxton location would be a closer and/or a more convenient option for the patients in that area, than the facility where they are currently dialyzing. The applicant also stated previously that Dr. Nestor had indicated that there were a significant number of patients living in the Maxton area who would transfer their care to a TRC facility in Maxton, upon certification. Once again, the applicant did not adequately demonstrate this assumption anywhere in the application. A demonstration by the applicant that the Maxton facility would be closer to the patients’ home would have supported the need to relocate the facility to the Maxton area. Furthermore, even if 21 patient support letters regarding in-center care were accepted at face value and projected forward based on the 5-Year AACR for Robeson County (2.6%), the applicant still does not adequately document how it arrives at 32 patients on a waiting list at the beginning of operating year one. Therefore, the applicant does not

adequately document the need to relocate St. Pauls Dialysis Center facility from St. Pauls to Maxton.

### Access

In Section VI, pages 36-39, the applicant describes how residents of the proposed service area, in particular medically underserved groups, will have access to the proposed services. On page 36, the applicant states:

*“Maxton Dialysis, 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.”*

On page 37, the applicant projects that 89.6% of the patients will be either Medicare or Medicaid recipients. The projected payor mix for Maxton Dialysis is based on projections submitted by the applicant in a previous application.

*“DaVita submitted a CON application in 2013 to develop a facility in Laurinburg in Scotland County. A study was conducted at that time to determine the payor mix for that facility. Since the proposed site was less than nine miles from the proposed site of the Maxton facility, the same payor mix was used.”*

The applicant adequately demonstrates that all residents of the area and in particular, medically underserved groups, are likely to have access to the proposed services.

However, the projected utilization provided by the applicant is not based on reasonable, credible and supported assumptions. The applicant does not adequately identify the population it proposes to serve or the need the proposed population has for a dialysis facility in Maxton. Therefore, the application is not 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 states that the relocation of St. Pauls Dialysis Center from St. Pauls to Maxton is needed because the St. Pauls Dialysis Center is currently underutilized, and will be forced to close due to low utilization. TRC proposes to relocate all 10 stations from St. Pauls to Maxton, approximately 36.8 miles away, according to MapQuest. The relocation of the facility from St. Pauls to Maxton does not appear to be geographically accessible to the



patients presently being served at the facility, as it is more than 30 miles away. The applicant previously stated that it is more convenient for a dialysis patient, particularly an in-center patient who dialyzes three times a week, to dialyze closer to the patient's home.

In Section III.6, page 23, the applicant states,

*“The TRC St. Pauls Dialysis Center patients will be given the option to transfer to another TRC facility. TRC operates facilities in Raeford in Hoke County, Red Springs in Hoke County (just over the county line from Robeson County) and in Elizabethtown in Bladen County. Of course, patients will be free to transfer to Maxton Dialysis. If a patient does not want to transfer to another TRC facility, the patients will have the option to transfer to one or more of the area Fresenius facilities. TRC Social Workers will help the patients with transfer to the facility of their choice.*

*The St. Pauls patients that will be remaining once the ten stations transferred upon completion of Maxton Dialysis should be accepted at the FMC St. Pauls facility. Representatives of TRC and the Medical Director will make contact with Fresenius at the appropriate time to discuss transfer of the TRC St. Pauls patients to the FMC St. Pauls facility. ...”*

The utilization rate for the facilities in which the applicant proposes to relocate the existing St. Pauls Dialysis Center patients is as follows:

Facility	City	# of Certified Stations	# of In-Center Patients	Utilization by Percent	Patients per Station
FMC St. Pauls	St. Pauls	13	44	84.62%	3.38
Dialysis of Hoke County	Raeford	30	110	91.67%	3.67
Lumbee River Dialysis*	Red Springs	-	-	-	-
Southeastern Dialysis Center Elizabethtown	Elizabethtown	24	68	70.83%	2.83

Source: January 2014 SDR data as of June 30, 2013

\*Lumber River Dialysis has been approved for 10 stations but not yet certified

As shown in the table above, two of the four facilities the applicant proposes to relocate patients are already operating over 80% capacity. One facility, Lumbee River Dialysis has been approved for a 10 station facility, but the stations are not yet certified. Southeastern Dialysis Center-Elizabethtown is the only facility that is currently operating below 80% capacity. However, Elizabethtown Dialysis is 30.9 miles from St. Pauls Dialysis, according to MapQuest. The St. Pauls Dialysis Center patients could reasonably be relocated to Lumbee River Dialysis upon certification, some may live close enough to relocate to Southeastern Dialysis Center-Elizabethtown, as these facilities would have the capacity to serve 16 additional in-center patients.

The applicant demonstrates that the needs of the population presently served at St. Pauls Dialysis Center will continue to be adequately met following the proposed relocation of the facility to Maxton. See discussion in Criterion 13 with regard to access by medically underserved groups, which is incorporated hereby as if set forth fully herein.

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 this application, which include:

- 1) Maintain the Status Quo – Keep the St. Pauls facility at the present location. The applicant states that the facility would eventually close due to a lack of patients. The facility has been operating only three days a week, according to the applicant, since it was certified. That option was not considered reasonable.
- 2) Relocate the facility to a contiguous county – The applicant states, *“That alternative was not considered since Robeson County has a surplus of eight stations. In order to consider transfer of ten stations across county lines, the losing county must have a surplus of at least ten stations and the gaining county has a deficit of at least 10 stations.”* Therefore, the applicant rendered this alternative unacceptable.

After considering those alternatives, the applicant states the alternative represented in the application is the best alternative.

However, the applicant did not adequately demonstrate the need to relocate the St. Pauls Dialysis facility from St. Pauls to Maxton for the following reasons:

1. The applicant did not adequately demonstrate the need to relocate the facility from St. Pauls;
2. The applicant did not adequately demonstrate why Maxton was the best site to relocate the facility;
3. The applicant did not adequately demonstrate that the Maxton Dialysis facility would in fact be closer to patients’ homes, than the facility where they are currently receiving treatment;
4. The applicant did not adequately demonstrate why it proposes patients are willing to transfer from Scotland County where there are currently two dialysis facilities, to Robeson County to dialyze at Maxton Dialysis; and

5. The applicant did not adequately demonstrate how any enhanced competition would have a positive impact on the proposed service area, including the effects of competition in Scotland County.

Furthermore, the application is not conforming to all other applicable statutory and regulatory review criteria, and thus, is not approvable. See Criteria (3), (5), (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 most effective alternative to meet the stated need. Therefore, the application is not conforming 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.

NC

In Section VIII.1, page 44 the applicant states the proposed capital costs of the project is \$1,628,049, which includes \$1,137,000 in construction costs; \$118,574 for RO water treatment equipment, \$73,730 for dialysis chairs, TVs, and patient computer systems; and \$298,745 for equipment, furniture, and consultant fees. In Section IX, page 48, the applicant projects that there will be no start-up expenses, initial operating expenses or working capital associated with the proposed project since this is an existing operating facility. However, it is not reasonable to project no start-up, initial operating and working capital expenses when proposing a new facility over 36 miles away with new patients. In Section VIII.2, page 45, the applicant states the entire capital cost of the project will be funded with cash reserves of DaVita Healthcare Partners, Inc., the parent company of Total Renal Care, Inc.

Exhibit 22 contains audited financial statements for DaVita Healthcare Partners, Inc. for the years ending December 31, 2013 and December 31, 2012. As of December 31, 2013, DaVita had \$946,249,000 in cash and cash equivalents. Exhibit 21 contains a letter dated April 11, 2014 from the Vice President of Tax for DaVita Healthcare Partners, Inc., which states in part:

*“I am the Vice President of Tax of DaVita HealthCare Partners, Inc., the parent and 100% owner of Total Renal Care, Inc. I also serve as the Vice President of Tax of Total Renal Care, Inc. which owns 85% of the ownership interests in Total Renal Care of North Carolina, LLC.*

...

*The project calls for a capital expenditure of \$1,628,049. This letter will confirm that DaVita HealthCare Partners Inc. has committed cash reserves in the total sum of \$1,628,049 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, LLC. ...”*

The applicant does not adequately demonstrate the availability of sufficient funds for the capital needs of the proposed project because it did not project any start-up expenses, initial operating expenses or working capital expenses.

In Section X.2, page 50 and Section X.4, page 53, the applicant provides projected revenues and operating costs (expenses), as illustrated in the following table:

<b>MAXTON DIALYSIS</b>		
	<b>OPERATING YEAR 1</b>	<b>OPERATING YEAR 2</b>
Total Net Revenue	\$1,686,667	\$1,753,000
Total Operating Costs	\$1,612,170	\$1,665,879
Net Profit	\$74,497	\$87,121

As shown in the table above, the applicant projects revenues will exceed expenses in the first two years of operation after completion of the project. The rates in Section X.1, page 49, are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services. However, the applicant does not adequately demonstrate that projected revenues and expenses are based on reasonable and supported projected utilization of the facility. See Criterion (3) for discussion which is hereby incorporated as if fully set forth therein.

Therefore, the applicant does not adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Consequently, the application is not conforming with 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.

NC

TRC proposes to relocate St. Pauls Dialysis Center from St. Pauls in northeastern Robeson County, to Maxton, in southwestern Robeson County. The facility is currently certified for 10 stations and provides in-center dialysis and peritoneal dialysis training and support. The applicant states that upon relocation of the facility, St. Pauls Dialysis Center will be renamed Maxton Dialysis. The applicant does not propose to increase the number of dialysis stations in the facility, and does not propose to acquire additional dialysis stations that would result in an increase in the inventory of dialysis stations in Robeson County.

As of June 30, 2013, St. Pauls Dialysis served 16 patients weekly on 10 dialysis stations, which is 40% of the facility's capacity  $[(16 / 10) / 4 = 0.4]$ . Dialysis facilities that operate four shifts per week (2 / day on alternate days) have a capacity of four patients per station. The applicant discusses projections for the in-center patient population in Section II, pages 14 – 16, and in Section III, pages 23 - 26 of the application. However, the applicant does not adequately explain how it arrives at 32 in-center patients to begin operating year one. The

applicant's projected utilization includes patients from Robeson, Scotland and Marlboro Counties. At the end of Operating Year One, Maxton Dialysis utilization is projected to be 3.2 in-center patients per station (32 patients / 10 dialysis stations = 3.2), or 80% of capacity. The growth projections are based on the Robeson County projected five-year average annual growth rate in the number of dialysis patients, as reported in the January, 2014 SDR.

According to the January 2014 SDR there are six dialysis facilities in Robeson County and two dialysis facilities in Scotland County; all eight of those facilities are operational with a total of 141 certified stations. Each of the eight facilities in Robeson and Scotland County is discussed below:

Facility	# of Certified Dialysis stations	# of Stations approved per CON conditional approval	# of In-Center Patients	Utilization by Percent	Distance to Maxton Dialysis
St. Pauls Dialysis	10		16	40.0%	36.76 miles
FMC St. Pauls	13		44	84.62%	37.05 miles
BMA of Red Springs	14		40	71.43%	13.86 miles
FMC Robeson County	23		66	71.74%	24.99 miles
FMC Pembroke	13		49	94.23%	10.92 miles
FMC Lumberton	30		104	86.67%	26.80 miles
FMC Scotland County	12	2	37	77.08%	7.65 miles
BMA Laurinburg	26	4	87	83.65%	6.93 miles
Lumbee River Dialysis	0	10	0	0	15.54 miles

Source: January and July 2014 SDR

As shown in the table above, the closest facilities to Maxton Dialysis are FMC Scotland County and BMA Laurinburg. The utilization rate for the FMC Scotland County facility is less than 80%, while the utilization for the BMA Laurinburg facility is over 80%. The applicant is proposing to serve 14 Scotland County in-center patients by the end of year one at the Maxton Dialysis facility. The 14 in-center patients the applicant is proposing will transfer to Maxton Dialysis are currently being served in Scotland County dialysis facilities with no documentation that the proposed Maxton site will be more convenient for them. Thus, the applicant did not adequately demonstrate the need for an in-center patient dialysis facility in Maxton serving over 40% ( $16 / 38 = .4211$ , or 42.1%) Scotland County patients. See the Need Analysis discussion in Criterion (3) which is incorporated hereby as if set forth fully herein. Therefore, the applicant did not adequately demonstrate that the proposal would not result in the unnecessary duplication of existing or approved in-center dialysis services in Scotland County. Consequently, 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 40, the applicant states that the St. Pauls Dialysis facility currently employs 8.9 full time equivalent staff (FTEs). The applicant further states on page 40, that the Maxton Dialysis facility proposes to hire .5 additional FTEs upon relocation of the facility to Maxton. Those FTE positions for which the applicant will hire are illustrated in the table below.

POSITION	PROPOSED FTEs
HTRN	0.5
<b>Total</b>	<b>0.5</b>

As shown in the above table, the applicant proposes to add a 0.5 full-time equivalent (FTE) position for a total of 9.4 FTEs to staff Maxton Dialysis during the first two operating years following project completion. On page 41, the applicant states that they anticipate no difficulty in hiring for any teammate openings that may occur at Maxton Dialysis. The following table shows the projected number of direct care staff for each shift offered in the facility following project completion, as reported by the applicant in Section VII.10, page 42:

	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

In Section V.4, page 33, the applicant states that Dr. Jonathan Nestor will serve as Medical Director of the facility. In Exhibit 15-16, the applicant provides letters of support from area physicians, one of which is signed by the proposed Medical Director. The applicant documents the availability of adequate health manpower and management personnel, for the provision of dialysis services. Therefore, the application is conforming to this criterion, subject to the following condition:

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

C

In Section V.1, page 31, the applicant provides a list of providers of the necessary ancillary and support services. Additionally, in Sections V.2 – V.7, on pages 32 – 35, the applicant provides further documentation of the availability of the necessary ancillary and support services for the patients to be served at Maxton Dialysis. Also see the applicant’s response to 10A NCAC 14C .2204, Section II, pages 16-17. The applicant adequately demonstrates

that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

C

In Section XI.2, page 55 of the application, the applicant states the proposed site of Maxton Dialysis will be located at 102 Pine Street in Maxton. In Section XI.2, page 55 and Section XI.6(h), page 61 of the application, the applicant states it will lease a shell building of 8,900 square feet, which Maxton Dialysis will upfit for the proposed dialysis facility in Maxton. The applicant proposes \$1,137,000 in construction cost, which is \$127.75 per sq.ft. ( $\$1,137,000 / 8,900$ ) for the proposed project. In Section XI.6(d), page 59 of the application,

the applicant states that applicable energy saving features and water treatment equipment will be incorporated into the construction plans by installing “...energy-efficient glass, mechanically operated patient access doors and energy-efficient cooling and heating.”

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. See Criterion (5) for discussion of costs and charges. 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(b), page 36, the applicant reports that 86.4% of the St. Pauls Dialysis patients who received treatment at St. Pauls Dialysis Center had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payment source of the facility:

SOURCE OF PAYMENT	PERCENTAGE
Medicare	22.7%
Medicaid	9.1%
Medicare/Medicaid	22.7%
Commercial Insurance	9.1%
VA	4.5%
Medicare/Commercial	31.9%
Total	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 Robeson and Scotland County and statewide.

COUNTY	2010 TOTAL # OF MEDICAID ELIGIBLES AS % OF TOTAL POPULATION *	2010 TOTAL # OF MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION *	2009 % UNINSURED (ESTIMATE BY CECIL G. SHEPS CENTER) *



Robeson County	31%	13.2%	23.9%
Scotland County	30%	12.9%	21.5%
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 Kerr Lake Dialysis. In fact, in 2011 only 5.8% of all newly-diagnosed ESRD patients (incident ESRD patients) in North Carolina’s Network 6 were under the age of 35.<sup>1</sup>

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 are 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 does 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. In addition, 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.”<sup>2</sup>*

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:

<sup>1</sup> Southeastern Kidney Council ESRD Network 6 2011 Annual Report; Table 3, page 16

<sup>2</sup><http://www.cms.gov/Medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf>

*“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.”<sup>3</sup>*

The report provides 2010 ESRD spending by payor, as follows:

<b>ESRD SPENDING BY PAYOR<sup>4</sup></b>		
<b>Payor</b>	<b>Spending in Billions</b>	<b>Percent 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%

In addition, the Southeastern Kidney Council (SKC) provides Network 6 [Georgia, North Carolina, and South Carolina] 2011 Incident ESRD patient data by age, race and gender, as shown below:

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<sup>3</sup>United States Renal Data System 2012 USRDS Report, Chapter 1, page 225:  
[http://www.usrds.org/2012/pdf/v2\\_ch1\\_12.pdf](http://www.usrds.org/2012/pdf/v2_ch1_12.pdf).

<sup>4</sup>United States Renal Data System 2012 USRDS Report, Chapter 11, page 340:  
[http://www.usrds.org/2012/pdf/v2\\_ch11\\_12.pdf](http://www.usrds.org/2012/pdf/v2_ch11_12.pdf).

<b>NUMBER AND PERCENT OF DIALYSIS PATIENTS BY AGE, RACE, AND GENDER</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	1529	16.4%
55-64	2370	25.4%
65-74	2258	24.2%
75+	1872	20.0%
<b>Gender</b>		
Female	4,237	45.35%
Male	5,105	54.65%
<b>Race</b>		
African-American	5,096	54.55%
White	4,027	43.11%
Other	219	2.3%
<b>Total</b>	<b>9,342</b>	<b>100.0%</b>

Source: Southeastern Kidney Council ESRD Network 6  
 2011 Annual Report; Table 3, page 16

The applicant demonstrates that it provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section VI.6 (a), page 39, the applicant states, *“There have been no civil rights 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(c), page 37, the applicant provides the projected payor mix for the proposed dialysis services at Maxton Dialysis as follows:

MAXTON DIALYSIS PROJECTED PAYOR MIX	
Source of Payment	Percentage
Medicare	21.9%
Medicaid	4.2%
Medicare/Medicaid	30.2%
Commercial Insurance	7.3%
VA	3.1%
Medicare/Commercial	33.3%
<b>Total</b>	<b>100.0%</b>

The applicant states on page 37 that,

*“DaVita submitted a CON application in 2013 to develop a facility in Laurinburg in Scotland County. A study was conducted at that time to determine the payor mix for that facility. Since the proposed site was less than nine miles from the proposed site of the Maxton facility, the same payor mix was used.”*

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion

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

C

In Section VI.5, page 38, the applicant states that:

*“Patients with End Stage Renal Disease will have access to dialysis services upon referral by a Nephrologist with privileges at Maxton Dialysis. These referrals most commonly come from primary care physicians or specialty physicians in Robeson County and surrounding counties or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact the Maxton Dialysis or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if it were found to be medically necessary [sic]. Patients from outside the Maxton Dialysis catchment area requesting transfer to this facility are processed in accordance with the Maxton Dialysis transfer and transient policies which compromise **Exhibit 17**. The*

*patient, again, is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary.” [Emphasis in original.]*

The applicant adequately demonstrates that it will provide a wide range of means by which a person can access the services. Therefore, the application is conforming to this criterion.

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

C

In Section V.3, page 33 of the application, the applicant states that “*Maxton Dialysis will be offered as a clinical learning site for nursing and CNA students at Robeson Community College.*” In addition, in Exhibit 14, the applicant provides a copy of an April 7, 2014 letter offering Maxton Dialysis as a clinical training site for nursing students at Robeson Community College. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity to this criterion.

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

NC

According to the January 2014 SDR, there are six dialysis facilities located in Robeson County: BMA Red Springs, FMC Robeson County, FMC Pembroke, FMC St. Pauls, Lumberton Dialysis and St. Pauls Dialysis. TRC, the applicant, proposes to relocate St. Pauls Dialysis Center from St. Pauls in northeastern Robeson County, to Maxton, in southwestern Robeson County. The facility is currently certified for 10-stations and provides in-center dialysis and peritoneal dialysis training and support. The applicant states that upon relocation of the facility, St. Pauls Dialysis Center will be renamed Maxton Dialysis. The applicant does not propose to increase the number of dialysis stations in the facility, and does not propose to acquire additional dialysis stations that would result in an increase in the inventory of dialysis stations in Robeson County.

In Section V.7, pages 34-35, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to dialysis services in Robeson

and Scotland County. See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access. The information in the application regarding quality and access is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates that it will continue to provide quality services; and
- The applicant adequately demonstrates that it will continue to provide adequate access to medically underserved populations.

However, the applicant does not adequately demonstrate that any enhanced competition includes a positive impact on the cost effectiveness of the proposed services based on the following analysis:

- The applicant did not adequately demonstrate that projected utilization is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.
- The applicant did not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of revenues and costs because projected revenues and costs are based, in part, on projected utilization. See Criterion (5) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.
- Development of a facility that is not needed is not cost effective.

Therefore, 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

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, St. Pauls Dialysis Center operated in compliance with the 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 proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C Section .2200. The specific findings are discussed below.

**SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES**

**.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- In Section IV.1, page 29, the applicant refers to the utilization rates for St. Pauls Dialysis as reported in the January 2014 SDR (provided in Exhibit 7 of the application). The utilization rate applied by the applicant was calculated based on 16 in-center dialysis patients and 10 certified dialysis stations as of June 30, 2013 (16 patients / 10 stations = 1.6 patients per station; 1.6 patients per station / 4.00 patients per station = 40%).

(2) *Mortality rates;*

-C- In Section IV.2, page 29, the applicant reports the 2011, 2012 and 2013 facility mortality rates for St. Pauls Dialysis as 12.0%, 4.8% and 30.7%, respectively.

(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, “Dialysis Care of Moore County provides home training for home hemodialysis patients under an agreement with St. Pauls Dialysis Center.”

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

- C- In Section IV.4, page 30, the applicant states, *“The St. Pauls Dialysis Center referred 6 patients for transplant evaluation in 2013. The St. Pauls Dialysis Center had one patient who received transplants in 2013.”*
- (5) *The number of patients currently on the transplant waiting list;*
- C- In Section IV.5, page 30, the applicant states, *“The St. Pauls Dialysis Center has one patient 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 30, the applicant states that there were 15 hospital admissions in CY 2013 for St. Pauls Dialysis, 4 of which (26.7%) were dialysis related, and 11 (73.3%) 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 30, the applicant states that there were no patients dialyzing at St. Pauls Dialysis Center with hepatitis B during 2013. The applicant further states there was one patient who had AIDS. There were no patients treated with infectious disease who converted to infectious status within the last year at St. Pauls Dialysis.
- (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.*
- C- In Exhibit 8, the applicant provides an April 14, 2014 letter signed by a representative of Scotland Memorial Hospital, which states the medical center will provide the following services to the proposed Maxton Dialysis facility:
- Acute dialysis
  - Emergency room care
  - Diagnostic evaluation services
  - X-Ray services
  - Special, immunological and routine laboratory services
  - Blood banking services
  - Surgical services including vascular surgery



- (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- In Exhibit 9, the applicant provides an April 8, 2014 letter signed by the Assistant Vice President of Carolinas Medical Center (CMC) which describes the relationship the hospital will have with Maxton Dialysis and the specific services that the hospital will provide to patients of Maxton Dialysis.
- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- In Section XI.6(e) and Section XI.6(f), on page 59 of the application, the applicant states that power and water will be available at the proposed site for the Maxton Dialysis facility. The applicant refers to Exhibits 10 and 11 for the documentation of the provision of these services; however, the documentation is actually provided in Exhibit 25.
- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- See Exhibit 10, in which the applicant provides copies of written policies and procedures for back up for electrical service in the event of a power outage.
- (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- In Section XI.1, page 52, the applicant provides information which identifies the location of the site on which the services are to be operated. In addition, in Exhibit 25, the applicant provides a copy of an April 14, 2014 letter signed by a representative of Hill/Gray Seven, LLC which evidences that DVA Healthcare Renal Care, Inc. will lease

the building in which it will provide dialysis services. In Section XI.3, page 56, and in Exhibit 25, the applicant identifies a secondary site on which the facility could be built.

(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 59, the applicant states, “Maxton Dialysis has and will continue to operate within the applicable laws and regulations pertaining to staffing and the fire safety equipment, physical environment and other relevant health safety requirements.” See Exhibit 12 for excerpts from the Health and Safety Policy and Procedure Manual and Exhibit 29 for the In-service Calendar with mandatory training classes.

(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- The applicant provides the following projected patient origin in Section III.7, page 23 of the application (see the analyst’s conclusions regarding the stated counties to be served by the facility):

**Projected Number of In-Center & Home  
 Dialysis Patients  
 First Two Operating Years**

COUNTY	OPERATING YEAR 1 (CY 2016)		OPERATING YEAR 2 (CY 2017)		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients	Year 1	Year 2
Robeson	17	4	18	5	55.3%	56.1%
Scotland	14	2	14	3	42.1%	41.5%
Marlboro, SC	1	0	1	0	2.6%	2.4%
<b>TOTAL</b>	<b>32</b>	<b>6</b>	<b>33</b>	<b>8</b>	<b>100%</b>	<b>100%</b>

See Section III.7, pages 23 - 26 of the application and the discussion in Criterion (3) with regard to the methodology and assumptions the applicant uses to project patient origin which is incorporated hereby as if set forth fully herein.

(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 the patients to be served at Maxton Dialysis will reside within 30 miles of the proposed 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 13, the applicant states,

*“Total Renal Care of North Carolina, LLC d/b/a Maxton 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.”*

**.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-

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

-NA-

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

-C- In Section II, pages 14-16 and Section III, pages 23-26, the applicant provides the assumptions and methodology used to project utilization for operating years one and two upon project completion. See Criterion (3) for discussion regarding the reasonableness of the applicant's assumptions.

**.2204 SCOPE OF SERVICES**

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

(1) *diagnostic and evaluation services;*

- C- The table in Section V.1, page 31, shows patients will be referred to Scotland Memorial Hospital for diagnostic and evaluation services.
- (2) *maintenance dialysis;*
- C- The table in Section V.1, page 31, shows the facility will provide dialysis and maintenance.
- (3) *accessible self-care training;*
- C- The table in Section V.1, page 31, shows self-care training will be provided by Dialysis Care of Moore County.
- (4) *accessible follow-up program for support of patients dialyzing at home;*
- C- See Section V, page 32. Accessible follow-up and support of patients dialyzing at home will be provided at Dialysis Care of Moore County.
- (5) *x-ray services;*
- C- The table in Section V.1, page 31, shows patients will be referred to Scotland Memorial Hospital for x-ray services.
- (6) *laboratory services;*
- C- The table in Section V.1, page 31, shows patients will be referred to Dialysis Laboratories for routine and special laboratory services.
- (7) *blood bank services;*
- C- The table in Section V.1, page 31, shows patients will be referred to Scotland Memorial Hospital for blood bank services.
- (8) *emergency care;*
- C- The table in Section V.1, page 31, shows patients will be referred to Scotland Memorial Hospital for emergency care.
- (9) *acute dialysis in an acute care setting;*
- C- The table in Section V.1, page 31, shows patients will be referred to Scotland Memorial Hospital for acute dialysis in an acute care setting. See Exhibit 8 for a copy of the proposed hospital transfer agreement.
- (10) *vascular surgery for dialysis treatment patients;*

-C- The table in Section V.1, page 31, shows patients will be referred to Scotland Memorial Hospital for vascular surgery for dialysis patients.

(11) *transplantation services;*

-C- The table in Section V.1, page 31, shows patients will be referred to Carolinas Medical Center for transplantation services. See Exhibit 9 for a letter from CMC which documents the transplantation services it will provide to Maxton Dialysis patients.

(12) *vocational rehabilitation counseling and services; and*

-C- The table in Section V.1, page 31, shows patients will be referred to North Carolina Division of Vocational Rehabilitation Services for vocational rehabilitation counseling and services.

(13) *transportation.*

-C- The table in Section V.1, page 31, shows patients will be referred to SEATS/DSS for transportation.

**.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 provides the proposed staffing. The applicant states, "*The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100 as evidenced below.*" Maxton Dialysis proposes two dialysis shifts, six days per week, and direct care staffing as noted in response to application question VII.10, page 42.

(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 Section VII.5, page 42, the applicant refers to Exhibit 20 for a copy of the training program outlines.