



November 2, 2015

Ms. Martha Frisone, Assistant Chief  
Healthcare Planning and Certificate of Need  
Division of Health Service Regulation  
North Carolina Department of Health and Human Services  
809 Ruggles Drive  
Raleigh, North Carolina 27603

Re: Public Written Comments  
CON Project ID # N-11077-15

Dear Ms. Frisone:

The attached Public Written Comments are forward for consideration by the CON Project Analyst conducting the respective review. If you have any questions regarding these comments please feel free to contact me.

Respectfully,

A handwritten signature in blue ink that reads "Jim Swann". The signature is fluid and cursive, with a long, sweeping underline that extends down and to the left.

Jim Swann  
Director of Operations, Certificate of Need

The application submitted by Total Renal Care of North Carolina, LLC (TRC) presents the CON Section with an incomplete picture, inaccurate information, and an application which is not conforming to the CON Review Criteria and Rules for End Stage Renal Disease Treatment facilities. The application should be not be approved, or conditionally approved. The following information identifies multiple failures within the application.

1. The application includes inaccurate information throughout the document. The applicant frequently refers to the facility as an existing facility. The reality is that TRC has proposed to relocate their St. Pauls dialysis facility to Maxton and rename the facility, Maxton Dialysis.

TRC does not yet have a Certificate of Need to relocate their facility.

TRC does not have an operational dialysis facility in Maxton.

Maxton Dialysis has not provided any dialysis care or treatment to any patients.

In response to Section A, Question 6, page 3, TRC indicates this is an existing facility. The CON analyst will find multiple references throughout the application to indicate Maxton Dialysis is an existing facility.

Maxton Dialysis simply does not exist today.

2. The response to Section A, Question 9, likewise infers Maxton Dialysis is an existing facility. See page 4.
3. The response to Section B, Question , page 8, is inaccurate. DaVita is the parent organization to both Dialysis Care of Hoke County and Lumbee River Dialysis centers in Hoke County. In short, DaVita is the only provider of dialysis services operating in Hoke County.

The Patient Origin Report for the period ended December 31, 2014, indicates that DC Hoke County was providing dialysis treatment for 80 Hoke County residents and the Lumbee River Dialysis was providing dialysis treatment for seven Hoke County residents. Thus, TRC should have indicated that they were serving 87 Hoke County residents, not 25.

In addition, BMA notes that all dialysis providers were required to file ESRD Data Collection Forms for the period ended June 30, 2015. The applicant would have had access to its own filings prior to submission of this application. The ESRD Data Collection form for DC Hoke County indicated that the facility was providing dialysis

care for 74 Hoke County residents as of June 30, 2015. The Lumbee River facility was providing dialysis treatment for another eight Hoke County residents. Thus, the applicant was providing dialysis treatment for 82 Hoke County residents as of June 30, 2015.

While the inaccuracies discussed here are not specific to any CON Review Criteria or Rule, the inaccuracies should cause the Analyst to question the veracity of the information within the application.

4. Speaking of inaccuracies, the applicant suggests on page 10 in response to Section B, Question 4, that the facility would be attended by Dr. Nestor, and “*other admitting nephrologists who directly oversee the quality of care of the dialysis facility.*” BMA asks, what other admitting nephrologists? The applicant has identified only a single nephrologist who will admit to the facility—Dr. Nestor. Again, the Analyst should review the application with full knowledge that it is replete with inaccuracies.
5. In the very next paragraph on Page 10 the applicant says that “*Maxton Dialysis “has always made dialysis services available to all residents...”* Really? Maxton Dialysis doesn’t even exist at this time.
6. The applicant clearly indicates on page 13 that the majority of proposed patients for the facility, greater than 61% in Operating Year 2, originate outside of Robeson County. There is no reason to expect that patients will leave Scotland County to receive dialysis care when there are existing facilities in Scotland County where they might receive dialysis care.  
  
The applicant proposes to serve these 33 Scotland County patients, but has provided no indication of transportation services which might be available to the patients.
7. On page 14, within the Applicant’s assumptions, the applicant blurs the lines related to the Robeson County dialysis station deficit. The need for stations within any county in North Carolina is based solely upon the number of ESRD patients residing within the county. A station deficit does not arise “*so there will be enough dialysis stations...to meet the needs...for patients living in contiguous counties...*” as suggested by the applicant.
8. The applicant fails to adequately support its patient projections for the facility. On page 14 the applicant suggests that growth of the patient census is based on 16 in-center patients who reside in Robeson County. The applicant has included only 13 patient letters of support, and only five of those are residents of Robeson County.

Furthermore, of the patient letters of support, only four are from patients dialyzing at the DaVita St. Pauls facility. Where does the applicant find 16 patients residing in Robeson County?

The applicant can not rely upon the prior CON application for Maxton: a Certificate of Need has not yet been awarded from that application.

9. The applicant suggests that 16 Scotland County patients will transfer their care to the Maxton facility. Yet, the applicant proposes to serve a total of 33 Scotland County patients in both Operating Year 1 and 2. The applicant has grossly overstated the number of patients to be served at the facility.
10. The applicant's Patient Census Projections: In-Center chart on page 15 is remarkably unclear. The applicant suggests the facility has 22 patients from December 31, 2014 through the certification date of the proposal.

The applicant suggests the census will more than double from 22 patients on December 31, 2016 to 45 patients on January 1, 2017. The applicant offers no reasonable, credible, or supported explanation for the census projections.

11. The applicant offers inconsistent information with regard to the number of PD patients at the facility. On page 7 of the application, the applicant indicates that the facility will "*open with seven PD patients...*" The chart on page 16 indicates that the facility will begin with only six PD patients.
12. Within the discussion for Criterion 4, on page 26, the applicant suggests that they have chosen this alternative to "*meet the growing demand for the patient population **living in and around Maxton***" [emphasis added]. However, the applicant is projecting to serve four patients (see letters of support) from the Laurel Hill area in Richmond County. Laurel Hill is not near Maxton. Furthermore, the applicant includes a letter of support from a patient residing in Red Springs; the DaVita Lumbee River Dialysis is much closer to the Red Springs patient population than Maxton.
13. The applicant suggests in response to Criterion 8, on page 41, that the nephrologists at Duke University Medical Center will provide medical coverage for the patients at Durham Dialysis. Obviously, this is not an application related to Durham Dialysis. Obviously the nephrologists from DUMC have not provided any letter of support.

But, more importantly, this is just another example of the many inaccuracies and inconsistencies within the application.

14. On page 50, within the discussion for Criterion 13, the applicant suggests that the DC Richmond County facility is the basis for the payor mix projections. Richmond County is not similar to Robeson County. See attached.

- As of July 1, 2014, the Robeson County population is 134,168, while the Richmond County population is only 45,733, equivalent to only 34% of the Robeson County population.
- The African-American population of Robeson County is only 24.7% of the population, equivalent to approximately 33,286 persons. The African American population of Richmond County is 31.4% of the population, but is approximately 14,360 persons. Thus, in raw numbers there are more than twice as many African-American persons residing in Robeson County.
- The American-Indian population of Robeson County is 39.7% of the population, equivalent to approximately 53,500 persons. The American-Indian population of Richmond County is only 3.1% of the population, or approximately 1,418 persons. Thus, in raw numbers, the American-Indian population of Robeson County is greater than 37 times larger than the American-Indian population of Richmond County.
- The Hispanic/Latino population of Robeson County is 8.1% of the population, equivalent to approximately 101,916 persons. The Hispanic/Latino population of Richmond County is 6.4% of the population, or approximately 2,927 persons. Thus, in raw numbers, the Hispanic/Latino population of Robeson County is greater than 3.7 times larger than the Hispanic/Latino population of Richmond County.
- A similar analysis of the population without health insurance reveals that there are more than 3 times as many persons in Robeson County without health insurance.
- And finally, a similar analysis of the population living in poverty indicates that there are more than 3 times as many persons in Robeson County residing in poverty.

This analysis is relevant if considered by the analyst within the light of the Randolph County ESRD review from 2010. In her Required State Agency Findings of March 4, 2011, CON Project Analyst Ms. Jane Rhoe-Jones noted on page 34, that “race

impacts the incidence of kidney disease”. Furthermore, poverty levels impact eligibility for Medicaid.

In the instant case, Robeson County has significantly more persons living in poverty and a much larger population of African-American and American-Indians. The applicant has failed to provide any documentation which supports its assertion that the payor mix in Robeson County will duplicate that of Richmond County. Thus, it is not reasonable to assume that these two counties are comparable in economic status.

15. The applicant indicates in Section N, Criterion 18a, page 55, that this expansion is not expected to have any impact on competition. Nothing could be further from the truth. The applicant is fully aware that this facility will impact Fresenius facilities in Robeson and Scotland Counties. Mr. Hyland of DaVita is the identified contact person for the application. Mr. Hyland of DaVita participated in the appeal (by Fresenius) of the CON Agency approval for the Maxton facility. While the Judge at OAH has rejected the BMA appeal, Mr. Hyland is clearly very aware that the Maxton facility will change the competitive landscape in Robeson and Scotland Counties.

In a recent dialysis CON contested case (the FMC Tar River case, 13-DHR-18127 and 13-DHR-18223), Ms. Lauren Coyle, a DaVita Regional Operations Director, testified that dialysis facilities necessarily relied upon the commercially insured patients to ensure a facility remained financially viable. Note the following copied from the court transcript.

*“So the type of work I'm doing is trying to analyze where we have or do not have a strong commercial mix among our patient base. So Medicare, just as you may read from the press and you can also read in our--you know, in the annual reports, Your Honor, Medicare doesn't pay a high enough rate for any of the dialysis providers to make any money off of-- we lose money on every single Medicare treatment we do. And this is really tough because--again, you can read just in the press and in DaVita's 10-K, 90 percent of our patients are Medicare patients.*

*So we rely on a really tiny patient base--as an industry, we rely on a really tiny patient base to make all of our money for us. We don't stay in business without these private pay or commercially insured patients. So you can easily see that one patient will--could send a clinic either into profitability or losing one patient could send a clinic out of profitability.”*

Transcript of Ms. Coyle, page 40

BMA would agree that the loss of a single commercially insured patient can have significant impact on the profitability of a facility. In this case, the applicant proposes to enlist the assistance of the Medical Director to refer existing patients away from the current provider, and transfer to a facility which is not needed in the area.

Given the bleak financial outlook for the existing facilities in the area, BMA suggests that it is not reasonable to add additional dialysis stations to the area and further dilute the payor mix. The application by TRC should be found non-conforming to CON Review Criterion 18a.

16. BMA suggests that failure to correctly identify the population to be served and the needs of that population for the services at Maxton should cause the analyst to determine the application is non-conforming to CON Review Criterion 3. Criterion 3 is not a Criterion which can be conditioned. The application should be denied.
17. BMA suggests that to the extent the applicant has failed on Criterion 3, then the applicant necessarily fails on CON Review Criterion 5. If the patient projections are unreliable, then the resultant financial projections are similarly unreliable. The applicant should be found non-conforming to CON Review Criterion 5.
18. The applicant seeks to unnecessarily duplicate existing health care resources. There are more than sufficient dialysis stations in Scotland County to meet the needs of the dialysis patient population residing in Scotland County. The applicant has proposed that greater than 60% of its proposed patient population would be residents of Scotland County. The application should be found non-conforming to CON Review Criterion 6.
19. The applicant has not provided any reliable information which supports using the payor mix from a Richmond County dialysis facility for a facility in Robeson County. The application should be found non-conforming to CON Review Criterion 13.
20. Given the many failures within the application, the application is clearly not the best alternative and fails to conform to CON Review Criterion 4.

#### SUMMARY:

The TRC application to relocate four dialysis stations to the facility in Maxton should be denied. BMA suggests the application fails on multiple levels and should not be approved. The application fails to conform to CON Review Criteria 3, 4, 5, 6 and 18a.

For these reasons, the application should be denied.


# US Census Bureau Quick Facts



	Robeson County, North Carolina	Richmond County, North Carolina
People		
Population		
<b>Population estimates, July 1, 2014, (V2014)</b>	<b>134760</b>	<b>45733</b>
Population estimates base, April 1, 2010, (V2014)	134168	46639
Population, percent change - April 1, 2010 (estimates base) to July 1, 2014, (V2014)	0.4	-1.9
Population, Census, April 1, 2010	134168	46639
Age and Sex		
Persons under 5 years, percent, July 1, 2014, (V2014)	7.2	6.2
Persons under 5 years, percent, April 1, 2010	7.6	6.6
Persons under 18 years, percent, July 1, 2014, (V2014)	25.9	23.6
Persons under 18 years, percent, April 1, 2010	26.8	24.4
Persons 65 years and over, percent, July 1, 2014, (V2014)	13	16.1
Persons 65 years and over, percent, April 1, 2010	11.2	14.3
Female persons, percent, July 1, 2014, (V2014)	51.6	51.1
Female persons, percent, April 1, 2010	51.4	50.8
Race and Hispanic Origin		
<b>White alone, percent, July 1, 2014, (V2014) (a)</b>	<b>32.2</b>	<b>62.4</b>
White alone, percent, April 1, 2010 (a)	29	60.2
<b>Black or African American alone, percent, July 1, 2014, (V2014) (a)</b>	<b>24.7</b>	<b>31.4</b>
Black or African American alone, percent, April 1, 2010 (a)	24.3	30.6
<b>American Indian and Alaska Native alone, percent, July 1, 2014, (V2014) (a)</b>	<b>39.7</b>	<b>3.1</b>
American Indian and Alaska Native alone, percent, April 1, 2010 (a)	38.4	2.5
Asian alone, percent, July 1, 2014, (V2014) (a)	0.8	1
Asian alone, percent, April 1, 2010 (a)	0.7	0.9
Native Hawaiian and Other Pacific Islander alone, percent, July 1, 2014, (V2014) (a)	0.1	0.1
Native Hawaiian and Other Pacific Islander alone, percent, April 1, 2010 (a)	0.1	0.1
Two or More Races, percent, July 1, 2014, (V2014)	2.6	2
Two or More Races, percent, April 1, 2010	2.5	2.1
<b>Hispanic or Latino, percent, July 1, 2014, (V2014) (b)</b>	<b>8.1</b>	<b>6.4</b>
Hispanic or Latino, percent, April 1, 2010 (b)	8.1	5.9
<b>White alone, not Hispanic or Latino, percent, July 1, 2014, (V2014)</b>	<b>26.6</b>	<b>57.6</b>
White alone, not Hispanic or Latino, percent, April 1, 2010	27	58.7
Population Characteristics		
Veterans, 2009-2013	7453	4027
Foreign born persons, percent, 2009-2013	5.6	4.2
Housing		
Housing units, July 1, 2014, (V2014)	52299	20976
Housing units, April 1, 2010	52751	20738
Owner-occupied housing unit rate, 2009-2013	64.9	64.4
Median value of owner-occupied housing units, 2009-2013	66800	77500
Median selected monthly owner costs -with a mortgage, 2009-2013	990	954
Median selected monthly owner costs -without a mortgage, 2009-2013	339	313
Median gross rent, 2009-2013	592	583
Building permits, 2014	140	197
Families and Living Arrangements		
Households, 2009-2013	45154	18254
Persons per household, 2009-2013	2.9	2.48
Living in same house 1 year ago, percent of persons age 1 year+, 2009-2013	88.4	86.7
Language other than English spoken at home, percent of persons age 5 years+, 2009-2013	8.8	6.8
Education		
High school graduate or higher, percent of persons age 25 years+, 2009-2013	71.5	80.1
Bachelor's degree or higher, percent of persons age 25 years+, 2009-2013	12.5	12.4
Health		
With a disability, under age 65 years, percent, 2009-2013	13	15.8
<b>Persons without health insurance, under age 65 years, percent</b>	<b>24.7</b>	<b>20.2</b>
Economy		
In civilian labor force, total, percent of population age 16 years+, 2009-2013	53.4	53.9

In civilian labor force, female, percent of population age 16 years+, 2009-2013	51	51.3
Total accommodation and food services sales, 2007 (\$1,000) (c)	128842	37720
Total health care and social assistance receipts/revenue, 2007 (\$1,000) (c)	561361	160464
Total manufacturers shipments, 2007 (\$1,000) (c)	2792640	697349
Total merchant wholesaler sales, 2007 (\$1,000) (c)	627050 D	
Total retail sales, 2007 (\$1,000) (c)	1337907	424114
Total retail sales per capita, 2007 (c)	10470	9232
Transportation		
Mean travel time to work (minutes), workers age 16 years+, 2009-2013	23	19.8
Income and Poverty		
Median household income (in 2013 dollars), 2009-2013	29806	32384
Per capita income in past 12 months (in 2013 dollars), 2009-2013	15343	17236
<b>Persons in poverty, percent</b>	<b>30.7</b>	<b>27.3</b>
Businesses	Robeson County, North Carolina	Richmond County, North Carolina
Total employer establishments, 2013	1800	842
Total employment, 2013	30207	11192
Total annual payroll, 2013	880123	327781
Total employment, percent change, 2012-2013	-4.4	2.5
Total nonemployer establishments, 2013	7398	2001
All firms, 2007	8420	2534
Men-owned firms, 2007	4173	1283
Women-owned firms, 2007	2677	661
Minority-owned firms, 2007	3755 S	
Nonminority-owned firms, 2007	4084	1979
Veteran-owned firms, 2007	817 S	
Nonveteran-owned firms, 2007	6876	2136
Geography	Robeson County, North Carolina	Richmond County, North Carolina
Population per square mile, 2010	141.3	98.4
Land area in square miles, 2010	949.22	473.82
FIPS Code	"37155"	"37153"

This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates

Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable. Click the Quick Info  icon to the left of each row in TABLE view to learn about sampling error.

The vintage year (e.g., V2014) refers to the final year of the series (2010 thru 2014). Different vintage years of estimates are not comparable.

- (a) Includes persons reporting only one race
- (b) Hispanics may be of any race, so also are included in applicable race categories
- (c) Economic Census - Puerto Rico data are not comparable to U.S. Economic Census data

D: Suppressed to avoid disclosure of confidential information

F: Fewer than 25 firms

FN: Footnote on this item in place of data

NA: Not available

S: Suppressed; does not meet publication standards

X: Not applicable

Z: Value greater than zero but less than half unit of measure shown