



**FRESENIUS
MEDICAL CARE**

October 31, 2013

Mr. Craig R. Smith, Chief
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603



Re: Public Written Comments, CON Applications
CON Project ID # N-10200-13
CON Project ID # N-10201-13
CON Project ID # N-10204-13
CON Project ID # N-10211-13 **L-10211-13**

Dear Mr. Smith:

Please find attached Public Written Comment for the above noted CON applications.

If you have any questions, please contact me.

Respectfully,

Jim Swann

Direct of Operations, Certificate of Need

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Raleigh, North Carolina 27612

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Public Written Comments
CON Project ID # L-10211-13
Total Renal Care, Inc., d/b/a
Nash County Dialysis
Prepared and submitted by Jim Swann
FMC Director of Operations, Certificate of Need



The Certificate of Need application submitted by TRC is non-conforming to multiple CON review criteria and rules. The application is not approvable. The application is not conditionally approvable. The following comments illustrate deficiencies within the application.

1. The applicant has provided an application based upon data known to be incorrect. BMA has provided DHSR Medical Facilities Planning Section with corrected information regarding the July 2013 SDR. The July 2013 SDR was produced by utilization of provided self-reported data. This was the first time the SDR has been compiled in this fashion. Unfortunately, there were errors in data reported by three BMA facilities (as well as other providers). This incorrect data led to the published Need Determinations within the July 2013 SDR. BMA is not suggesting that the SDR does not include the Need Determinations as noted by the applicant.

The incorrect data led to a grossly exaggerated Five Year Average Annual Change Rates. TRC has utilized a rate of 9.6% as the Nash County Five Year Average Annual Change Rate. The information provided by BMA to the Medical Facilities Planning Section (and to all dialysis providers operating in NC) clearly demonstrates that a more correct growth rate would have been less than one fourth of that employed by TRC, 2.1%.

If TRC had utilized a more correct 2.1%, their calculations would have produced projected year end census information as is indicated below. BMA has replicated the TRC methodology (from the application, beginning on page 31) below and changed the annual growth rate to 2.1%:

Date	Patients	X	Growth Rate	=	Year End Census
Begin, September 1, 2013	26				
September 1, 2013 through December 31, 2013	26	X	1.007 (4 Months)	=	26.182
January 1, 2014 through December 31, 2014	26.182	X	1.021	=	26.732
January 1, 2015 through June 30, 2015	26.732	X	1.0105 (6 Months)	=	27.013
July 1, 2015 through June 30, 2016	27.013	X	1.021	=	27.580
Add 6 Wilson County Patients End Operating Year 1	27.580	+	6	=	33.580
July 1, 2016 through June 30, 2017	27.580	X	1.021	=	28.159
Add 6 Wilson County Patients End Operating Year 2	28.159	+	6	=	34.278

Rule 10A NCAC 14C .2203 (a) requires an applicant proposing to establish a new End State Renal Disease facility shall document the need ... based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility. In this case the applicant has proposed to develop a 12 station dialysis facility. Thus the applicant would be required to demonstrate service to at least 38.4 patients, rounded to 39 patients, at the end of the first year of operations. In this case, if the applicant had utilized a more correct annual growth rate of 2.1%, the applicant would have failed to meet the requirements of this rule.

BMA does suggest that the applicant knew the information which led to the SDR included incorrect data. A copy of the same corrected information provided to DHSR Medical Facilities Planning Section was sent to Mr. William L. Hyland of DaVita Healthcare Partners as well as all other providers of dialysis services in North Carolina.

Procedurally, Medical Facilities Planning received the information from BMA as a petition to the SHCC. The SHCC Long Term and Behavioral Health Committee met on September 11, 2013. The BMA petition was presented to the Committee with a recommendation from the Medical Facilities Planning Section to accept the petition and correct the SDR going forward. The Committee agreed. Mr. Hyland of DaVita Healthcare Partners was present at this meeting. This was fully four days in advance of the filing date of the CON applications arising from this incorrect need determination.

Subsequent to filing the applications, the full SHCC met on October 2, 2013 where upon the recommendations of the Long Term and Behavioral Health Committee were accepted. Thus, the next SDR, January 2014, will have

corrected information regarding county ESRD census, and corrected county five year average annual change rates.

The point of all of this is that while the Need Determinations as published can not be an issue within a contested case hearing (a contested case hearing arising from this review is a very real possibility), in point of fact, all parties—the applicant, BMA, Medical Facilities Planning Section, the SHCC Long Term and Behavioral Health Committee—knew that the need determination was based upon faulty data.

Given the foreknowledge of the errors, it would have been prudent for the applicant to have chosen an alternative course. Alas, we are forced to contend with an application based upon faulty data.

The applicant has knowingly used an incorrect number as its beginning point for the Nash County ESRD patient population as of December 31, 2013.

The applicant has knowingly utilized an incorrect county five year average annual change rate in its projections of future patient populations to be served by the proposed facility.

Consequently, the applicant has knowingly prepared and filed a certificate of need application which is not reasonable, and is not based upon a reasonable foundation.

In the Brunswick County Contested Case, 08 DHR 0818, (arising from a competitive ESRD CON review, applications filed September 2007), Acting Division Director Horton cited to the “Craven” case” in his Findings of Fact number 68:

From the Final Agency Decision, 08 DHR 0818, Findings of Fact:

68. Projections attempt to predict something that will occur in the future; therefore, the very nature of a projection cannot be established with absolute certainty. Craven, 176 N.C. App. at 52-53, 625 S.E.2d 837, 841. Projections of a patient census made in a CON application thus conform to Criterion 3 as long as the projections are “reasonable.” (ALJ Finding 65.).

The very foundational numbers employed by Total Renal Care in its application are not reasonable. If they are not reasonable, then they must be rejected by the CON Project Analyst. Consequently the application is non-conforming to Review Criterion 3.

Further, because the financial projections of the applicant are based upon a faulty foundation, the financial projections are therefore unreasonable and non-conforming to Review Criterion 5.

Thus, the applicant has provided an application which can not be approved and is therefore not the most effective alternative. The application is non-conforming to CON Review Criteria 4.

2. The applicant has provided letters of support which are non-specific and unreliable. None of the letters of support provided by the applicant specify where the patient may reside within the county of residence. The CON Section has a long history of close scrutiny of patient letters of support. The patient letter of support must convey some sense of how the new facility would be more convenient.

The patient letters of support provided by the applicant do not specify any area of the county that the patient may reside. With a single exception, none of the patient letters of support indicate that the patient resides within Nash County. However, Nash County is a land area of 540 square miles. Wholesale acceptance of non-specific letters such as included in this application is an invitation to all CON applicants to provide vague data and insist that the CON Section accept such as absolute.

Absent any definition of where in Nash County the patient may reside, the CON Analyst must reject the patient letters as non-specific. Absent a clear indication of the proposed facility as a more convenient alternative, the applicant has failed to identify the needs of the population to be served.

3. The applicant has provided vague and unreliable information regarding its quality programs. On page 26 of the application the applicant refers to "*a nearly 205 reduction in gross mortality...*" What is the 205?
4. On page 28 of the application the applicant refers to a "*detailed analysis*" with regard to where to site the facility. There is no relevant discussion of this analysis. There is no information other than the conclusion. How can the CON Analyst conclude that the applicant has conducted a detailed analysis?
5. The applicant has offered information on page 35 in response to III.9 regarding the number of facilities operated by FMC and DaVita in surrounding counties. The question speaks to alternative methods for meeting the needs of the proposed project. The CON application process is not a State contrived effort to promote or discourage competition. Rather it is a State effort to ensure appropriate distribution of health services for the citizens of our State. All applicants must prove their need case with reasonable projections. What is point of this element of the response offered by the applicant? It does not address any of the relevant CON review criteria or rules.
6. The applicant indicates on page 35 that the facility will utilize single-use dialyzers. However, the floor plan included at Exhibit 35 does include a "re-use" room, or a room for processing dialyzers for re-use. Is the facility a single-use

facility? If so, the applicant has not provided a line drawing which is truly representative of the planned facility operations. The application is therefore non-conforming to CON Review Criterion 12.

If the facility is not going to be a single-use facility, then the applicant has provided an application which is internally inconsistent.

7. On page 43 the applicant has suggested that approval of the TRC application would not have *“any adverse effect on competition within Nash County.”* This is absolutely incorrect.

Nash County is not an economically affluent county. The following information was obtained from the North Carolina Department of Commerce website: <https://www.nccommerce.com/research-publications/incentive-reports/county-tier-designations>.

“The N.C. Department of Commerce annually ranks the state’s 100 counties based on economic well-being and assigns each a Tier designation. The 40 most distressed counties are designated as Tier 1, the next 40 as Tier 2 and the 20 least distressed as Tier 3.”

Nash County has been ranked in Tier 2. Nash County ranks in the middle of the economic picture in our State.

The BMA CON applications for BMA Rocky Mount (CON Project ID # L-10182-13), filed on September 16, 2013, clearly reflects the economics of Nash County.

Consider the amount of bad debt for BMA Rocky Mount as reported within the CON application:

BMA bad debt in BMA Rocky Mount was in excess of \$1 million for FY 2012.

Further, compare BMA estimates of Bad Debt for Operating Year 1 and 2 to the TRC (DaVita) estimates of Bad Debt for Operating Year 1 and 2.

Bad Debt Comparison		Operating Year 1	Operating Year 2
BMA	Bad Debt	\$ 388,767	\$ 399,714
	Total Projected TX	19108	19543
	Bad Debt / TX	\$ 20.35	\$ 20.45
TRC	Bad Debt	\$ 46,683	\$ 51,352
	Total Projected TX	6669	7336
	Bad Debt / TX	\$ 7.00	\$ 7.00

Approval of the TRC application, which is based upon data known to be faulty, will jeopardize the financial performance of existing facilities in Nash County. Consequently the application is not conforming with CON Review Criterion 18a.

Given this failure on 18a, the application can not be considered as the most effective alternative and therefore fails to conform to CON Review Criterion 4.

8. The applicant has provided an application which is based upon current Medicare reimbursement and fails to consider the reality of probable cuts to Medicare reimbursement. Any changes to Medicare reimbursement for dialysis care will become public record during the pendency of this CON application review. The CON Analyst should not fail to consider such changes as they are announced.
9. The application contains multiple internal inconsistencies. For example, the applicant suggests on page 59 of the application that it will hire all new teammates for the facility. However, the applicant has apparently told the patients that teammates would be transferring to the new facility (see patient letters of support).
10. In several locations within the application, the applicant refers to Laurinburg and Scotland County. This is an application for Nash County. Laurinburg is a road trip of approximately 150 miles from Rocky Mount (via I-95 to US 74).
11. The applicant has included an Exhibit 18 which is specific to Scotland County and does not address Nash County in any sense.

In addition to the preceding comments, BMA notes that the CON Project Analyst will also complete a comparative analysis of the CON applications arising from the Nash County Need Determination as published in the July 2013 SDR. BMA offers the following comments regarding a comparison of the TRC application and the BMA applications. The comparative factors are those used in other recent dialysis competitive reviews.

SMFP Principles

a. Home Training

TRC proposed to provide home training for Peritoneal Dialysis and home hemodialysis.

BMA provides home training for both Peritoneal Dialysis and Home Hemodialysis.

Both TRC and BMA are equal with regard training.

b. Hours of Availability

TRC has proposed to be operational from 6:00 AM to 4:00 PM.

FMC Nash County has proposed to be operational from 6:00 AM to 5:00 PM.
BMA Laurinburg has proposed to be operational from 6:00 AM to 5:00 PM.

Both TRC and BMA are equal with regard to hours of operation.

c. Services in rural, remote areas

Both applications are based in Rocky Mount, Nash County. Nash County is a rural county but not remote. Therefore both applications are equal with regard to this factor.

Facility Location

The TRC proposal is on the same street as BMA Rocky Mount. Both TRC and BMA are equal with regard to location.

Access by underserved groups

TRC and BMA have provided similar tables reflecting access by underserved groups:

Provider	Medicaid / Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
TRC, Nash County Dialysis	5.4%	15%	86.5%	51%	52%
BMA Rocky Mount	28.3%	46.2%	79.9%	48.9%	83.7%

As the table reflects, the TRC application is woefully inferior with regard to Medicaid and Low-Income patients, the elderly, and racial minorities. The applications are comparable on service to Medicare beneficiaries and women.

Service to Nash County Residents

BMA is an existing provider within Nash County and is serving Nash County residents. However, TRC has suggested that it is serving Nash County patients in other locations. Therefore, both applicants may be considered equal on this factor.

Access to Alternative Providers

Not applicable. Both providers are currently serving Nash County residents.

Thus, both applications may be viewed as equal with the exception of Access by Underserved Groups. BMA is superior in this regard.

Conformity with Review Criteria and Rules.

The BMA applications for BMA Rocky Mount is fully conforming to all review criteria and rules. The TRC application fails to conform to Review Criteria 3, 4, 5, 12, and 18a. Therefore the BMA application is more effective.

Conclusion: The TRC application is non-conforming to Review Criteria 3, 4, 5, 12, and 18a and is therefore un-approvable.

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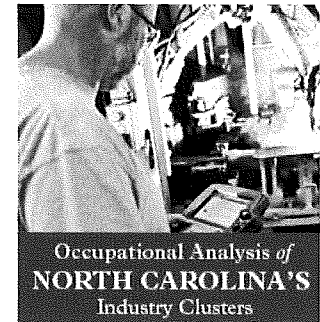
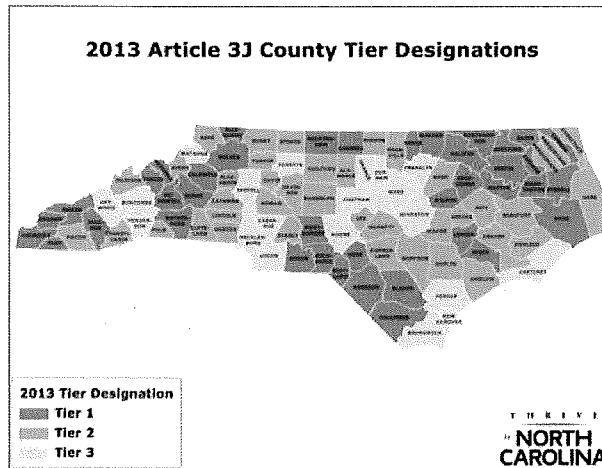
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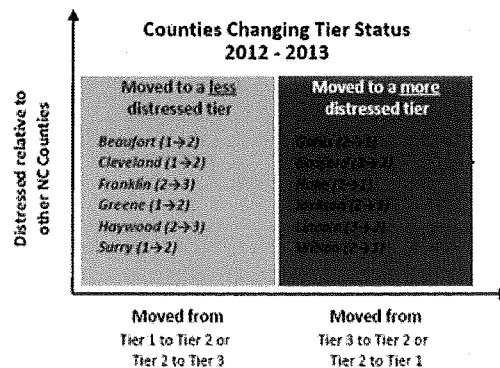


2013 County Tier Designations

The N.C. Department of Commerce annually ranks the state's 100 counties based on economic well-being and assigns each a Tier designation. The 40 most distressed counties are designated as Tier 1, the next 40 as Tier 2 and the 20 least distressed as Tier 3.

This Tier system is incorporated into various state programs, including the Article 3J Tax Credits, to encourage economic activity in the less prosperous areas of the state. Please see the 2013 County Tier Designations for a detailed view of designations.

Note: Article 3J Tax Credits should not be confused with Article 3A William S. Lee (WSL) Tax Credits. Article 3J is not a revision of the Lee Act; it replaces it. In general, William S. Lee Credits are repealed for business activities that occur on or after January 1, 2007 and Article 3J Credits take effect for taxable years beginning on or after January 1, 2007. Please see the 2013 County Tier Designations for a detailed view of designations.



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Click the county name to view the current county profile. To sort, click the *county* or *tier designation* in the head of the table.

County	Tier Designation
Alamance	2
Alexander	2
Alleghany	1
Anson	1
Ashe	2
Avery	2
Beaufort	2
Bertie	1
Bladen	1
Brunswick	3
Buncombe	3
Burke	1
Cabarrus	3
Caldwell	1
Camden	1
Carteret	3
Caswell	1
Catawba	2
Chatham	3
Cherokee	1
Chowan	1
Clay	1
Cleveland	2
Columbus	1
Craven	2
Cumberland	2
Currituck	2
Dare	2
Davidson	2
Davie	2
Duplin	2
Durham	3
Edgecombe	1
Forsyth	3
Franklin	3
Gaston	2
Gates	1
Graham	1
Granville	2
Greene	2
Guilford	2
Halifax	1

Harnett	2
Haywood	3
Henderson	3
Hertford	1
Hoke	1
Hyde	1
Iredell	3
Jackson	1
Johnston	3
Jones	1
Lee	2
Lenoir	1
Lincoln	2
Macon	2
Madison	2
Martin	1
McDowell	1
Mecklenburg	3
Mitchell	1
Montgomery	1
Moore	3
Nash	2
New Hanover	3
Northampton	1
Onslow	2
Orange	3
Pamlico	2
Pasquotank	2
Pender	3
Perquimans	2
Person	2
Pitt	2
Polk	2
Randolph	2
Richmond	1
Robeson	1
Rockingham	1
Rowan	2
Rutherford	1
Sampson	2
Scotland	1
Stanly	2
Stokes	2
Surry	2
Swain	1
Transylvania	2
Tyrrell	1
Union	3
Vance	1
Wake	3
Warren	1

Washington	1
Watauga	3
Wayne	2
Wilkes	1
Wilson	1
Yadkin	2
Yancey	1

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