FRESENIUS MEDICAL CARE

Received by the CON Section APR 1 2013

April 1, 2013

Jane Rhoe-Jones, Project Analyst
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, N.C. 27603

Re: Public Written Comments / CON Project ID # M-10083-13 / Total Renal Care, Inc., d/b/a/ Sampson County Home Dialysis

Dear Ms. Rhoe-Jones:

On behalf of Bio-Medical Applications of North Carolina, Inc., and Bio-Medical Applications of Clinton, Inc. I am forwarding the following public written comments regarding the Total Renal Care (TRC) CON application to develop a free standing home program in Clinton, Sampson County, North Carolina.

1. The applicant has used an exaggerated growth rate of 9.5% to project a patient population to be served. Consequently projections of future patient populations are overstated.

   The January 2013 SDR reports that Sampson County Five Year Average Annual Change Rate for dialysis patient population is only 3.0%. The SDR similarly reports that Duplin County five year average annual change rate was only 3.3%. In both cases, the home patient population is included in the 5 year average annual change rate. The applicant has failed to provide any substantive support for a growth rate of 9.5%.

   It is not appropriate to suggest that a population which has been increasing in the 3% range is going to somehow miraculously triple that growth and increase at a rate of 9.5%.

   Statewide the home dialysis patient population comprises approximately 12.4% of the dialysis patient population [1841 / 14863 = .1239, or 12.4%]. Thus, it is logical to conclude that the growth in the Sampson and Duplin County home dialysis patient populations has essentially reached its peak and will now begin to slow such that the ESRD patient populations of these two counties will mirror that of the State as a whole. The applicant has not provided any rationale or explanation as to why the ESRD patient population of these counties should be considered to be different from the entirety of North Carolina.

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As an additional consideration, the Applicant has not addressed the differences within home dialysis between peritoneal dialysis and home hemo-dialysis and changes in those respective patient populations.

The Southeastern Kidney Council has for many years published zip code reports indicating ESRD patient populations by zip code across North Carolina. BMA has reviewed zip code reports for the period ending December 31, 2007, December 31, 2009, and March 31, 2012 (the last published report available). The data in the following table is extracted from these reports and addresses the North Carolina ESRD patient population.

Census Date	In-Center	Home HD	Home PD	IC PD	Other	Total
3/31/2012	12836	277	1420	2		14535
12/31/2009	12128	123	1186	1	6	13444
12/31/2007	11704	59	1115		6	12884

The data indicates the following changes over the 51 months from December 31, 2007 to March 31, 2012:

	In-Center	Home HD	Home PD	Total
Raw Change	1132	218	305	1651
Percent of Change	0.096719	3.694915	0.273543	0.128143
Annualized Change	0.022757	0.869392	0.064363	0.030151

Thus, it becomes obvious that while the statewide ESRD patient population experienced an annualized change rate of 3% over this period, the home hemo-dialysis patient population changed by 86.9% annually while the PD patient population changed by only 6.4% annually.

The information above supports the assertion that the applicant has utilized a growth factor far and above the statewide growth factor for peritoneal dialysis patients. The Applicant has ignored the differing growth factors in the PD and home hemo-dialysis populations and has used a growth factor of 9.5% for a PD only patient population. The applicant is proposing a growth factor 148% higher than that experienced by the PD population within our State. The application is therefore non-conforming to CON Review Criterion 3. Further, the CON Section has traditionally held that Criterion 3 is not a criterion that may be conditionally approved.

2. To the extent that the applicant fails to adequately identify the patient population to be served, the resultant financial projections of revenues are therefore based upon unreliable projections of patient treatments. Consequently, the application is non-conforming to CON Review Criterion 5 and is not approvable.

3. The applicant has not provided "a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital" that is capable of providing acute dialysis treatment for the ESRD patients of the facility. The Rule at 10A NCAC 14C .2202(b)(1) states:

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

For the benefit of the Analyst, BMA notes that 42 CFR, Section 405.2100 has been changed to 42 CFR Section 494.

BMA notes for the Project Analyst that 42 CFR 494.180 requires the dialysis facility to have "an identifiable governing body". One requirement of the governing body is to ensure that the dialysis facility must have an agreement with a hospital that can provide inpatient care. Relevant portions of the Code are below:

> *"§ 494.180 Condition: Governance.*
>
> *The ESRD facility is under the control of an identifiable governing body, or designated person(s) with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility.*

(g) Standard: Emergency coverage. (1) The governing body is responsible for ensuring that the dialysis facility provides patients and staff with written instructions for obtaining emergency medical care.

(2) The dialysis facility must have available at the nursing/monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called, and how they can be reached.

(3) ***The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week****. The agreement must:*

(i) Ensure that hospital services are available promptly to the dialysis facility's patients when needed.

(ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies."

(Emphasis added by BMA).

The applicant has provided a letter of intent from Sampson Regional Medical Center. Sampson Regional Medical Center does not currently offer acute dialysis services. Further, the hospital has not offered acute dialysis services within the most recent 12 months. Nor has the hospital filed a Certificate of Need application seeking to add acute dialysis services to its service offerings.

Absent a recent history (within past 12 months) of providing acute dialysis services, the addition of acute dialysis services at Sampson Regional Medical Center would be classified as a New Institutional Health Service pursuant to GS 131E-176 (16)(d). Thus it would appear that the applicant has proposed to refer patients to a hospital that does not have the ability to provide acute dialysis care and treatment.

Within the application submitted by Total Renal Care, the **only** letter with a hospital provided by the applicant is a letter from Sampson Regional Medical Center (Application Exhibit 6). Therefore the applicant is not conforming to 10A NCAC 14C .2202(b)(1) and should be denied.

4. Further complicating the issue is the applicant's assertion that it would refer patients to the Cape Fear Valley Hospital (CFVH) in Fayetteville. The nephrology physicians supporting this proposal do not have admitting

privileges at CFVH. Absent hospital privileges, who, or which nephrology physicians would be responsible for care of the patient admitted to CFVH? There is no indication within the application that the physicians supporting the proposal would seek admitting privileges at CFVH.

the applicant has proposed a project which does not provide for the full gamut of health care services normally needed by ESRD patients and as required by 42 CFR 494. The application is therefore not approvable.

5. The applicant incorrectly assumes that the FMC Roseboro facility will limit, or restrict, admission to the facility home dialysis program. Within the CON application to develop the Roseboro facility, BMA made the following statements:

   BMA is not projecting any change to the Home Patient population. The home patient population of Sampson County is ***currently comprised of only four patients*** *according to the SEKC Zip Code data for October 1, 2008. Since this is a new home program, and would be closer for patients of Sampson County, BMA* ***does expect that two of the four patients would transfer their care*** *to the new FMC Roseboro facility upon certification of the project. BMA has experienced increasing patient interest in home therapies in recent years. Until this program is certified, Home patients would have to travel to Fayetteville for home training and monthly home patient visits. With the development of this program in Roseboro,* ***BMA realistically expects to see more patients choose the home dialysis modality.*** *However,* ***for the purposes of this application, BMA will project that only two patients*** *will choose to transfer their care to the FMC Roseboro facility.*

   (Emphasis added by BMA).

   At the present time, the FMC Roseboro facility has one home dialysis patient who has completed training, one patient in training and two patients waiting to begin training.

6. The applicant has offered at floor plan at Exhibit 29 with a clear reference to home hemo-dialysis training stations. There are three rooms labeled PD-HHD. Within the industry, PD refers to Peritoneal Dialysis (the predominant home dialysis modality) and HHD refers to Home Hemo-Dialysis.

   In our State the Certificate of Need Section has determined that home hemo-dialysis training and support requires dialysis stations. Further, the CON

Section has denied at least two CON applications (DaVita, Union County / BMA, Cabarrus County) wherein an applicant proposed to include home hemo-dialysis stations in a facility with less than 10 dialysis stations. Therefore, the application is non-conforming to Review Criterion 12.

Summary:

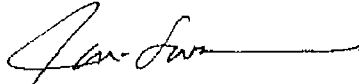
Taken as a whole, BMA suggests that the application submitted by Total Renal Care Inc., seeking to develop a free-standing peritoneal dialysis facility in Clinton, Sampson County, North Carolina, is not approvable. The application fails to conform to CON Review Criteria 3, 5 and 12. The application fails to conform to the Rule at 10A NCAC 14C .2202 (b)(1) because the application fails to conform to CFR 494.180(g)(3).

For the forgoing reasons, the Application for Sampson County Home Dialysis should be denied.

Upon further review, BMA may determine that other non-conformities exist.

If you have any questions or I can be of further assistance, please feel free to contact me at 919.896.7230 or via email, jim.swann@fmc-na.com.

Sincerely,



Jim Swann, Director
Market Development and Certificate of Need