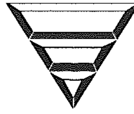
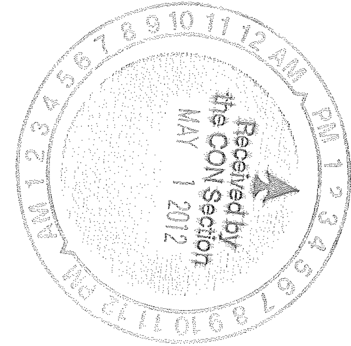


**Fresenius Medical Care**




May 1, 2012

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

Re: Public Written Comments for the Macon County Dialysis Competitive Review, 7-Station Need Determination Pursuant to the January 2012 SDR

Dear Mr. Smith:

On behalf of Bio-Medical Applications of North Carolina, I am forwarding the following as Public Written Comments regarding the CON Application submitted by Total Renal Care, CON Project ID # A-8799-12 for the Macon County Dialysis Need Determination. BMA is pleased to have the opportunity to submit comments, and hope that the CON Project Analyst will consider these comments during the review process.

1. The applicant has failed to appropriately address Basic Principle 12 as stated within Chapter 14 of the 2012 SMFP. Basic Principle 12 notes that the *"North Carolina State Health Coordinating Council encourages applicants for dialysis stations to provide or arrange for: a. Home training and backup for patients suitable for home dialysis in the ESRD dialysis facility that is a reasonable distance from the patient's residence;"* Indeed, TRC has proposed to develop a seven station dialysis facility in Franklin, Macon County, N.C. pursuant to the adjusted need determination as published within the January 2012 SDR. However, TRC has suggested that it will not provide home hemo-dialysis training and support at its proposed facility in Franklin.

   The very nature of the adjusted need determination leading to this application was to remedy and provide relief for the dialysis patients of Macon County who have been required to travel over mountainous terrain to a dialysis facility in another county. Surely the SHCC did not intend to exclude home hemo-dialysis patients from consideration when it approved the petition leading to this adjusted need determination.

3725 National Drive, Suite 130
Raleigh, N.C. 27612
Phone: 919-896-7230 FAX: 919-896-7233

2. The applicant has utilized a methodology which is internally inconsistent and overstates the projected population to be served by the facility. Thus, the application fails to satisfy Review Criterion 3. Consider the following:

   The applicant has utilized differing growth rates for its projections of patients to be served. In projecting its in-center patient population, the applicant has used the Macon County Five Year Average Annual Change Rate of 3.8%. BMA has used a similar growth rate.

   However, in projecting the growth rate for its home patient population, the applicant has used a growth rate of 12.5%. This is not consistent with basic mathematical principles, and therefore grossly overstates the home patient population to be served.

   The SDR projects the ESRD patient population of each North Carolina County, (with the exception of two multi-county service areas, each NC county is a distinct service area). The SDR calculations essentially take the whole of the county ESRD patient population and project this population to increase (or decrease) consistent with the published county five year average annual change rate. Consequently the entire population of the County should be increased at the same rate, in this case 3.9%.

   It is not reasonable to project a portion of the population to increase at a one rate, and project the remaining population to increase at a second, and different rate. To do so is inconsistent with methodology employed within the SDR and ultimately endorsed by the SHCC.

   Consider the following for illustrative purposes:

   The January 2012 SDR Table B reports that the Macon County ESRD patient population as of June 30, 2011 was 29 patients. The SDR further projects the Macon County ESRD patient population to be 30.1 patients as of June 30, 2012. This number was calculated by multiplying the 29 patients (as of June 30, 2011) times 3.8% and then adding the 29. In the alternative this could be stated as 29 X 1.038.

   (29 X 0.038) + 29 = 30.1

   However, using the methodology employed by TRC creates a totally different number. The SDR reports that the 29 Macon County ESRD patients as of June 30, 2011 were comprised of 23 in-center patients and 6 home dialysis patients. The following illustrates the methodology used by TRC:

   (23 X 0.038) + 23 = 23.87
   ( 6 X 0.125) + 6 = 6.75
   TOTAL = 30.62, rounded to 30.6

   Thus, in a single 12 month period, the methodology employed by TRC overstates the patient population by 0.5 patients. This 0.5 patient ultimately becomes 2 patients by the proposed end of Operating Year 1.

This error is significant in light of the following:

**<u>From the Final Agency Decision, 08 DHR 0818, Findings of Fact:</u>**

*65. There is no specific methodology that must be used in determining patient origin under CON law. Retirement Villages, Inc. v. N.C. Dep't of Human Resources, 124 N.C. App 495, 500, 477 S.E.2d 697, 700 (1996). Rather, what is required is that all assumptions including the methodology, must be stated. 10A N.C. Admin. Code 14C.2202(b)(6), .2203(c). (ALJ Finding 62).*

*66.* ***The CON Section reviews need methodology for "analytical, procedural, and mathematical correctness" in order to determine whether an application is conforming to the statutory and regulatory criteria.*** *Britthaven, 118 N.C. App. At 388, 455 S.E.2d at 462. (ALJ Finding 63).*

*[emphasis added by BMA]*

Furthermore:

**<u>From the Final Agency Decision, 08 DHR 0818, Findings of Fact:</u>**

*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.).*

*[emphasis added by BMA]*

The projections of patient population to be served are neither mathematically correct, nor are they reasonable. Consequently, the application should be found non-conforming to Review Criterion 3.

In multiple discussions with Mr. Craig Smith, Chief of the CON Section, Mr. Smith has always maintained that Need can not be conditioned. Thus, based upon the foregoing, the application submitted by TRC should not be found conforming to Criterion 3, nor should it be found conditionally conforming.

3. As a function of failing to satisfy Criterion 3, the applicant has therefore offered overstated projections of revenue, rendering the application non-conforming to Review Criterion 5. Consequently the applicant is also non-conforming to Review Criterion 4.

4. The application offers internal inconsistency with regard to staffing. On page 31 of the application, the applicant has apparently represented to the patients proposed to transfer to the facility that the same staff will be working in their Macon County Dialysis facility.

However, on page 52 of the application the applicant says that they will *"hire all new teammates for the facility three months prior to the projected opening date."*

The obvious question before the CON Section, and ultimately the patients of the proposed facility is: Will there be continuity of care by having the same staff, or will there be all new staff at the proposed Macon County Dialysis?

5. On page 42 of the application, the applicant says: *"We would not expect to receive patient transfer request from dialysis facilities whose patients live in their home county."*

   The statement is troublesome. Will TRC restrict admissions to their proposed facility?

6. The applicant has offered questionable information with regard to equipment needs. Table XIII.1 reflects only $92,190 for dialysis machines. On page 48 the applicant proposes to purchase dialysis machines for $13,170. This is a proposal for a seven station facility. Seven, multiplied by $13,170 is equal to $92,190. The applicant has apparently not planned or budgeted for any back-up dialysis machines.

   Dialysis machines are indeed machinery. They require routine preventative maintenance. They will on occasion become inoperative and need maintenance. How will the applicant address the need for equipment and provide treatment with no back-up machines?

In addition to the above, BMA offers the following brief comparative analysis:

1. The BMA application projects to serve more Medicare and Medicaid patients. The payor mix for the two applications is as follows:

| Payor Mix | BMA | TRC |
|---|---|---|
| Medicare | 81.5% | 79.7% |
| Medicaid | 6.3% | 3.1% |
| Commercial | 9.8% | 7.8% |
| VA | 1.5% | 9.4% |
| Self/Indigent | 0.9% | 0.0% |
| Total | 100.0% | 100.0% |

   BMA is the more effective alternative.

2. The proposed staff salaries are not reported in identical formats in Table X.5. However, in an effort to set the tables equal, BMA has backed out the TRC proposed Medical Director costs, and added in the TRC proposed staff taxes and benefits. The following table demonstrates total staff costs and costs per treatment.

| Salary Expense Table X.5 | BMA | | TRC | |
|---|---|---|---|---|
| Year 1 | $ | 329,074 | $ | 389,480 |
| Year 2 | $ | 338,946 | $ | 400,730 |
| Average Salary Expense / Treatment | | | | |
| Year 1 | $ | 94.21 | $ | 84.23 |
| Year 2 | $ | 93.14 | $ | 79.01 |

The question for the CON Section is, which proposal will invest more in staff per treatment? BMA suggests that a lower salary cost per treatment should not be read as more favorable within a comparative analysis; quite the opposite, a higher staff cost per treatment will lead to higher staff morale and better retention, ultimately translating into a higher quality and continuity of care for the patient. Thus, BMA is the more effective alternative.

3. BMA proposes to offer a full complement of dialysis services to include home hemo-dialysis training and support. TRC proposes that home hemo-dialysis patients should continue to travel to Sylva for training and support. Thus, BMA is the more effective alternative.

4. Both applicants offer essentially the same revenue per treatment projections. However, the CON Analyst should consider that TRC has overstated the patient population to be served (see comments regarding Criterion 3). If TRC had provided more reasonable projections of the population to be served it is probable that the revenue per treatment would compare more favorably for BMA.

| NET REV, Table X.2 | | | | |
|---|---|---|---|---|
| Year 1 | $ | 1,138,188 | $ | 1,497,113 |
| Year 2 | $ | 1,187,180 | $ | 1,642,188 |
| Average Revenue / Treatment | | | | |
| Year 1 | $ | 325.85 | $ | 323.77 |
| Year 2 | $ | 326.24 | $ | 323.78 |

5. The TRC application appears to offer a lower cost per treatment. However, the CON Analyst should consider that TRC has overstated the patient population to be served (see comments regarding Criterion 3). If TRC had provide more reasonable projections of the population to be served it is probable that the expense per treatment would compare more favorably for BMA.

| Expenses, Table X.4 | | |
|---|---|---|
| Year 1 | $ 1,095,443 | $ 1,355,506 |
| Year 2 | $ 1,140,432 | $ 1,459,786 |
| Average Expense / Treatment | | |
| Year 1 | $ 313.61 | $ 293.15 |
| Year 2 | $ 313.39 | $ 287.81 |

6. BMA direct patient care staff salaries are comparable to or more effective than those of TRC. BMA RN salary is $24.95 as opposed to TRC proposed RN salary of $25.00. However, BMA proposed salary for Patient Care Technicians is $15.80 as opposed to TRC proposed Patient Care Technician salary of $12.50. Thus, BMA is the more effective alternative.

If you have any questions, or I can be of further assistance, please contact me at 919-896-7230.

Sincerely,

Jim Swann
Regional Director of Health Planning