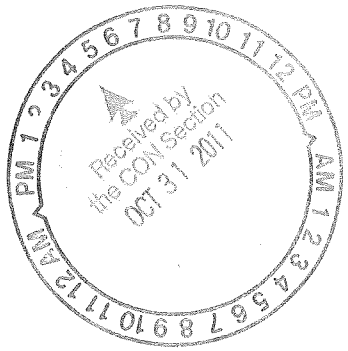
Fresenius Medical Care



October 31, 2011

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, CON Project ID #C-8733-11

Dear Mr. Smith:

On behalf of Bio-Medical Applications of North Carolina, I am forwarding the attached as Public Written Comments regarding the CON Application filed by DCI to add four dialysis stations to its facility for a total of 14 stations. 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.

BMA is of the opinion that its application to develop a new facility in Shelby and the DCI CON applications to expand can be approved by the CON Section. Both applicants propose to serve patients currently being served coupled with growth of their respective patient populations. Notwithstanding the suggestion that all three applications can be approved, BMA offers the following comments.

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

Sincerely,

Jim Swann, via email

Jim Swann
Director, Market Development and Certificate of Need

Attachment: Public Written Comments

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

Public Written Comments
Re: CON Project ID # C-8733-11
Dialysis Clinic, Inc.
d/b/a DCI Boiling Springs
Prepared and submitted by: Jim Swann
FMC Director, Market Development and Certificate of Need

1. The applicant has provided an unreasonable need methodology in its representations of patients to be served. An applicant for a Certificate of Need must provide reasonable estimates of the patient population to be served. BMA notes the following Findings of Fact from the Final Agency Decision, 08 DHR 0818, (the BMA Brunswick County contested case hearing).

   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).

   In the case at hand, BMA believes the "analytical" approach by DCI to be unreasonable. The applicant has demonstrated growth of its patient population based upon the facility specific growth over a period of one year rather than the County Five Year Average Annual Change Rate. While an applicant is free to utilize and support a growth rate other than that published within the SDR, in this case the applicant has used a growth rate of 46%. Contrast that with the Cleveland County Five Year Average Annual Change rate of only 4.1%.

2. While BMA does not agree with the utilization of the exceptionally high growth rate as discussed above, BMA also notes that DCI has capped its facility at 56 patients, and does not demonstrate further growth of a patient population which increases every year.

3. The applicant has also suggested that it does not plan to operate a third dialysis shift unless or until there is a demand from the patient population. This is inconsistent with the SMFP which *"encourages applicants for dialysis stations to provide or arrange for...ESRD dialysis service availability at times that do not interfere with ESRD patient's work schedules..."*

4. The applicant has not included any indication of state or federal income taxes to be paid.