



May 31, 2013

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



Re: Public Written Comments
CON Project ID # P-10123-13, New River Dialysis
CON Project ID # K-10124-13, Kerr Lake Dialysis
CON Project ID # K-10126-13, Youngsville Dialysis

Dear Mr. Smith:

On behalf of Bio-Medical Applications of North Carolina, Inc., I am forwarding the following public written comments regarding the above referenced CON projects.

Please accept the attached comments as denoted for each project. 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,

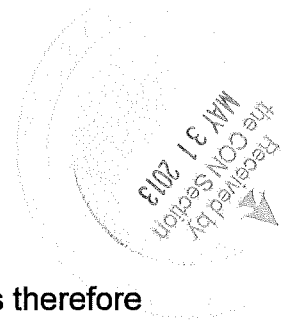
A handwritten signature in cursive script, appearing to read "Jim Swann".

Jim Swann, Director
Market Development and Certificate of Need

Market Development and Certificate of Need

3717 National Drive, Suite 206
Raleigh, North Carolina 27612

Phone 919-896-7230
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1. The application is not conforming to the CON review schedule and is therefore not conforming to Review Criteria 1. The applicant proposes to transfer dialysis stations across county lines from Wake County into Franklin County. The CON Review Schedule as established within the SMFP clearly indicates that this should be considered a Category D CON application. The Review Schedule for Category D calls for applications of this nature to be filed in March and September for reviews beginning on April 1 or October 1.
2. Further, the applicant is non-conforming to Policy ESRD-2. ESRD-2 allows for the transfer of existing certified dialysis stations. In this case the applicant has recently been approved to add 5 dialysis stations to its Wake Forest dialysis facility. These stations are not yet certified. Thus, the applicant can not transfer these stations.
3. The applicant fails to provide a response to 10A NCAC 14C.2202 (a) (1). The applicant suggests that information regarding utilization of the Dialysis Care of Franklin County may be found in response to IV.1 of the application. However the information in IV.1 apparently refers to another CON application and does not provide information relevant to the DC Franklin County facility.
4. The applicant fails to provide a sufficient number of patient letters of support. The applicant has included 28 patient letters of support for the in-center station transfer and suggests that two other patients have voiced their intent to transfer with the successful completion of the project. However, as BMA has noted in the past, and as Mr. Smith, CON Section Chief has indicated on multiple occasions, patient letters of support are the evidence which the CON Section relies upon. Indeed, as BMA has noted in past comments, patient letters of support are the "gold standard".
5. The assumptions regarding the DC Franklin County facility capacity are hollow and self serving. The DC Franklin County facility has been underutilized for several years. The fact that the facility can not be physically expanded is of no import when the facility has been consistently operating below the 80% utilization threshold. Consequently, this is not the best alternative and the application is therefore non-conforming to Review Criterion 4.

6. To the extent that the applicant has relied upon its representations of 2 patients to transfer, and absent and clear evidence of the patient's intent, the applicant fails to meet the requirements of 10A NCAC 14C.2203a.
7. The applicant has posited that one of the foundational elements of this application is to make service more convenient for the patient. However, the applicant is proposing that patients who may be candidate for transplantation must travel to Charlotte. This is a one way commute in excess of three hours. The applicant has failed to provide a credible consideration for the patients of the facility when there are two nationally acclaimed transplantation programs within an hour of the proposed facility: Duke UMC and UNC Hospitals.
8. The applicant has failed to appropriately consider all existing and certified health service facilities in the County which provide dialysis services. The applicant has alluded to the Fresenius facilities in neighboring counties. However, the applicant has not addressed the existing home training facility operated by Fresenius, and located within Youngsville. To the extent that the new facility proposes to offer PD services, the applicant is seeking to duplicate existing services which are available for patients of the Youngsville area. The application is therefore non-conforming to Review Criterion 6 and should be denied.
9. The applicant's financial projections are unreliable. The applicant provides no explanation for its number of projected treatments in Section X of the application. Within the Year 1 projections, the applicant proposes that 6396 treatments could be performed (before allowance for missed treatment). Dialysis patients receive 3 weekly treatments for a total of 156 possible treatments annually. Divide 6396 by 156 and the result is 41 patients. However, within the Table provided in response to III.7, the applicant proposes to serve a total of 42 patients in the first year. Where does the number 41 come from? Is this a calculation error? Is this to suggest that the applicant will provide charity care for one patient for the entirety of the year? There simply is no answer provided. The Project Analyst can not know with certainty.
10. The applicant's site information is unclear and questionable. Which Site is the primary and which is the secondary. The information contained within the application appears contradictory to the information contained within the exhibit. As an additional comment, the site map provided for the primary site appears to be a map of the Raleigh Durham Airport—in Wake County, not Franklin County.

Public Witten Comments
CON Project ID # K-10126-13
Youngsville Dialysis
Prepared and Submitted by Jim Swann
FMC Director, Market Development and Certificate of Need

11. The information contained within the Table of facility square footages does not seem to indicate any space for the PD treatment area. How much space is dedicated to the PD training area? Thus once must question the application with regard to Criterion 12.

Summary: BMA suggests the application fails on multiple levels. The application is a Category D application and is not filed appropriately. Additionally, the application fails to conform to Policy ESRD-2. Consequently the application is non-conforming to Review Criterion 1. Further, the application is non-conforming with Review Criteria 3, 4, 5, 6, and 12. In addition, the application is non-conforming to Rule 10A NCAC 14C .2202(a)(1) and .2203a.

For these reasons, the application should be denied.