



December 2, 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 Project ID # F-10219-13,
DVA Healthcare Renal Care, Inc., d/b/a Huntersville Dialysis

Dr. Mr. Smith:

Please accept this letter as Public Written Comment for the above noted CON Project.

The Certificate of Need application submitted by DVA Healthcare Renal Care 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 not adequately identified a patient population to be served. The applicant has relied upon nine (9) patient letters of support from patients residing in Charlotte zip codes, and not residing in Huntersville, Cornelius or Davidson zip codes. There are existing dialysis facilities with capacity for additional patients within these zip codes. Further, there is no compelling reason for patients to transfer their care to a new facility in Huntersville when existing capacity is available in a convenient setting.

The CON Section has previously established that it would not be appropriate to approve a CON application for dialysis stations in Huntersville when patients who reside south of Huntersville in zip codes 28216 and 28269 would bypass a closer dialysis facility in order to reach the proposed facility in Huntersville. Clearly, patients residing in these zip codes could continue dialysis at the DaVita North Charlotte facility, or could transfer to the DaVita North Charlotte facility from another DaVita facility which is seemingly further from the proposed location in Huntersville. (See Required State Agency Findings for FMC Huntersville, CON Project ID # F-8284-09).

The applicant is not conforming to CON Review Criterion 3.

2. As an additional consideration with regard to Criterion 3, one must question the source of referrals for future patients at the proposed facility.
 - Dr. Wood, the proposed Medical Director is presumably a retired nephrology physician. Is Dr. Wood returning to private practice and will Dr. Wood be admitting patients to the facility? The applicant has not provided any indication that Dr. Wood will admit patients.
 - Rather, what the applicant has suggested is that Metrolina Nephrology Associates (MNA) will refer patients to the facility. This is not what Dr. Bruce has represented in his letter. Dr. Bruce has suggested that MNA will follow ESRD patients of the MNA practice who "choose" to dialyze at the facility. This statement does not say that MNA will refer patients to the facility.
3. To the extent that the applicant has failed meet the requirements of Criterion 3, the applicant further fails on Criterion 5. If the applicant's projections of a population to be served are unreasonable, then the financial projections of revenue are likewise unreasonable.
4. Because the applicant is non-conforming to Criterion 3 and 5, the applicant is likewise non-conforming to Criterion 4. The applicant has not provided the best alternative by this proposal.
5. The applicant has provided an application which is based upon current Medicare reimbursement and fails to consider the reality of recnt cuts to Medicare reimbursement. Changes to Medicare reimbursement for dialysis care have been published as of November 27, 2013. Medicare has proposed a 9% reduction to reimbursement over a period of three years. The first year of this proposal is 2014; thus the third year, resulting in a 9% reduction to Medicare reimbursement for dialysis will become effective in 2016, Operating Year 1 of this proposal. The CON Analyst should not fail to consider such changes as they have been brought to the attention of the CON Section during the pendency of this review.
6. The applicant has not provided any discussion with regard to the Fresenius INS Peritoneal Dialysis facility operated on Kincey Avenue in Huntersville. The applicant therefore proposes to duplicate existing health services and is non-conforming to Criterion 6.

BMA will appear at the public hearing to speak in opposition to the proposal by DVA Healthcare Renal Care. BMA may offer additional comments at the public hearing.

If you have any questions, or I may be of further assistance, please contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "Jim Swann". The signature is fluid and cursive, with a long horizontal stroke at the end.

Jim Swann
Director of Operations, Certificate of Need