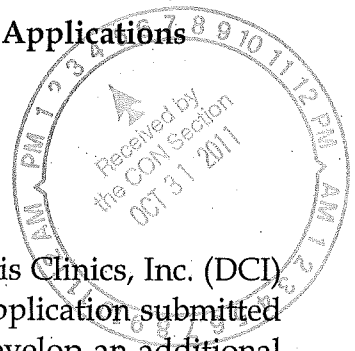
Competitive Comments on Cleveland County ESRD Applications

submitted by

DCI, Inc.



In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Dialysis Clinics, Inc. (DCI) submits the following comments related to the competing application submitted by Bio-Medical Applications of North Carolina (BMA) to develop an additional dialysis clinic in Cleveland County. DCI's comments include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards.*" *See* N.C. GEN. STAT. § 131E-185(a1)(1)(c). In order to facilitate the Agency's ease in reviewing the comments, DCI has organized its discussion by issue, specifically noting the general CON statutory review criteria and specific regulatory criteria and standards creating the non-conformity relative to each issue, as they relate to the application submitted by BMA.

BMA's application should not be approved as proposed. DCI has identified several specific issues, each of which contributes to BMA's non-conformity. Please note that relative to each issue, DCI has identified the statutory review criteria and specific regulatory criteria and standards creating the non-conformity.

BMA's proposal would have a negative impact on geographic access

One of the central tenets of the ESRD methodology and policies is the geographic distribution of dialysis treatment facilities. BMA itself attempts to describe its project as enhancing geographic access to its patients, yet its proposal fails to adequately address the need in Cleveland County. In particular, two facilities in the county have an immediate need for additional stations: DCI Shelby and DCI Boiling Springs. BMA fails to explain how its proposed single facility will provide adequate geographic access to patients when the need for additional stations is at two facilities in the county, one of which would be closer to the majority of BMA's patients in the southern part of the county.

Most critically, BMA's application proposes to have patients travel farther for care than they currently do. BMA has attempted to argue that its project would enable patients it treats from Cleveland County at its facilities in other counties to be treated within their home county. However, its proposed location in Shelby is actually farther away from the majority of the patients it currently serves. As shown on Map 1 in Exhibit 27 of its application (and as reproduced as Attachment 1 of these comments), most Cleveland County patients who are

treated at BMA facilities are from the Kings Mountain area of the county. BMA unreasonably believes it would be more reasonable to transfer a station from its well-utilized facility in Kings Mountain along with stations from other counties, and force patients to come to its facility in Shelby for care. This relocation would clearly not expand access to patients, but would impose geographic barriers that do not currently exist.

The fact that this is not in the best interests of patients is borne out in the *2011 State Medical Facilities Plan* which states in Chapter 14, Basic Principles 10: "Patient access to In-center ESRD Services: As a means of making ESRD services more accessible to patients, one of the goals of the N.C. Department of Health and Human Services is to **minimize** patient travel time to and from the center."

Chapter 14, Basic Principles 10.b states: "In areas where it is apparent that patients are currently traveling more than 30 miles for in-center dialysis, favorable consideration should be given to proposed new facilities which would serve patients who are farthest away from **existing, operational or approved facilities**." While BMA argues that the new Shelby clinic will be less than 30 miles from patients' homes and, thus, in conformance with the Basic Principles, the fact that BMA is proposing to establish a new clinic in an area **father away from**, not closer to, its patients and also which is in closer proximity to "existing, operational or approved facilities" is not in keeping with the intent of the Basic Principles and not proposing an improvement in access for these patients. Further, DCI Shelby is less than ½ mile from the proposed primary site. The proposed site for the BMA clinic does not meet these patient access goals of the *SMFP*.

BMA also lacks any analysis regarding why patients from Cleveland County are currently utilizing the various BMA facilities. Given the fact that two facilities already exist in Shelby, it is clear that patients are choosing a more distant facility for other reasons. For instance, if patients from the northern part of the county are going to Lincolnton or Hickory, they are already bypassing care in Shelby, likely because of other factors, such as better road access or caregiver travel patterns into those other towns. The development of another facility in Shelby will not expand access to those patients, who already have access to two facilities in Shelby. Moreover, BMA fails to demonstrate why the development of a third facility in Shelby, where two existing facilities already exist, would enhance access to patients who already have access in Shelby.

Due to these deficiencies, the BMA application should be found non-conforming with Criterion 3, and should be found to be a less effective alternative in the comparative analysis.

BMA's proposal would limit access for existing patients in Cleveland County

BMA proposes to develop a facility in Shelby, which, as discussed above, would not address the need in the southern part of the county, in Boiling Springs in particular, and would require patients to travel farther for care. Moreover, the approval of BMA's facility would prevent the much-needed expansion of DCI's Boiling Springs facility. As shown in that application, the annual growth rate for that facility is more than 46 percent and the need for expansion is critical; BMA's proposal does nothing to address that need. Moreover, by suggesting that some of BMA's Cleveland County patients from its other facilities will be cared for at BMA's proposed facility in Shelby, the growth represented by the patients currently seeking care at the existing facilities in the county will go unmet. As such, BMA fails to address the need being driven by patients treated within Cleveland County.

The failure to meet the need of the current patient population in Cleveland County is described on page 57 of BMA's application, in which the applicant states that it does not assume that it will treat DCI patients; rather, it assumes DCI patient populations will continue to increase. If that is true, then the existing DCI facilities need to expand in order to meet the need of their existing patient populations.

Due to these deficiencies, the BMA application should be found non-conforming with Criteria 3 and 6, and should be found to be a less effective alternative in the comparative analysis.

BMA fails to demonstrate that its methodology is reasonable

On pages 58 through 60, BMA outlines its methodology, which begins with the 26 in-center patients from Cleveland County that it currently treats at various facilities. It notes that the letters of support from these patients indicate that they might be willing to relocate to the new center, which will be closer to their homes than the center from which they currently receive care. While the application does contain letters of support, they are form letters, which do not indicate any actual analysis performed by the patients regarding the proposed center location. Nor do the letters or any other documentation provide evidence that care is not currently available at DCI's facilities in Shelby. As shown on the BMA map in Attachment 1, it is clear that the majority of BMA's Cleveland County patients are, in fact, closer to another existing BMA facility than they would be to the proposed Shelby site. This fact, combined with the tentative nature of the language from the patients (e.g. would "consider" relocating) minimizes the reliability of these letters to support the BMA methodology.

The methodology then unreasonably assumes (in the table on page 59) that 100 percent of its 26 existing patients would transfer to the new facility, resulting in 32 and 34 in-center patients during its first two project years, respectively, after its projected patient growth rate. As discussed above, the BMA map makes it clear that at least some of its existing patients would have to travel longer distances to the proposed Shelby facility as compared to existing BMA and even existing DCI facilities. Moreover, dialysis patients often must coordinate their treatments with caregivers and others who drive them to the center and back home. Given these factors, as well as the tepid language of the support letters, DCI believes that it is more reasonable to assume that at least some of BMA's existing patients would not choose to be treated at the proposed facility. If it is reasonable to believe that even one of BMA's patients might choose another facility, including the facilities they currently use, then its methodology is unreasonable.

A final flaw with the patient home analysis utilized by BMA is that it fails to consider the nature of ESRD care. While such an analysis might be appropriate to represent patient locations and travel patterns for other health care services, dialysis patients are much different than other patients receiving health care. As noted above, many of them rely on friends, family or other sources for transportation. Unlike securing a ride for a one-time outpatient surgery or other procedure, ESRD patients must have a commitment for three days per week, every week. Patients may choose to be treated at a facility that is more convenient for their source of transportation, rather than choosing one that is closer to home. (Moreover, as discussed in detail above, BMA fails to demonstrate that all of its patients would be closer to the proposed facility, even if that were the only consideration.) Finally, the unfortunate reality of dialysis care is a relatively high mortality rate, particularly for those that are ineligible for transplantation or who cannot timely find a suitable donor. As such, the location of one or even a handful of existing patients is not always the most appropriate methodology for determining the most effective location for a facility.

Due to these deficiencies, the BMA application should be found non-conforming with Criteria 3 and 5, and should be found to be a less effective alternative in the comparative analysis.

BMA fails to comply with Policy ESRD-2

(1) *Demonstrate that the proposal shall not result in a deficit in the number of Dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and,*

First, BMA provides conflicting information in its application that brings into question its intent in its proposal. On page 43 BMA proposes to transfer two stations from BMA Burke, six stations from BMA Hickory, one station from BMA Lincolnton, and ***one*** station from BMA Kings Mountain for a total of ten dialysis stations. However, on page 55, the applicant proposes to relocate two dialysis stations from BMA Burke County, six dialysis stations from BMA Hickory, one dialysis station from BMA Lincolnton, and ***two*** dialysis stations from BMA Kings Mountain for a total of eleven dialysis stations.

Moreover, as discussed below, BMA fails to demonstrate that each of its facilities treats a number of Cleveland County patients corresponding to the number of stations it proposes to relocate from each county. This is in conflict with the intent of this policy, in that BMA failed to demonstrate that any asserted relocation of patients from the four other counties would align with the number of stations being shifted from those counties.

Due to these deficiencies, the BMA application should be found non-conforming with Policy ESRD-2, Criteria 1, 3 and 3a, and should be found to be a less effective alternative in the comparative analysis.

<u>BMA fails to demonstrate adequate physician support</u>

As a facility that treats patients who have chronic disease and often have multiple co-morbidities, coordination with physicians and the health care system is essential. BMA states on page 58 that its proposed medical director will seek privileges at Cleveland Regional Medical Center. However, given emergency call and other requirements of medical staff privileging, it is unclear whether the medical director would be willing to assume all the responsibilities necessary to becoming part of the Cleveland County medical community. In contrast, all of DCI's nephrologists are active members of the Cleveland County medical community and have developed extensive relationships with local physicians, with whom they regularly coordinate care for their mutual patients.

Based on this issue, the BMA application should be found non-conforming with Criterion 7 and should be found to be a less effective alternative in the comparative analysis.

<u>BMA fails to demonstrate reasonable staffing</u>

The proposed BMA medical director's office is in Gastonia, 27 miles and 37 minutes from the proposed Shelby site. In contrast, the DCI medical directors'

offices are located across the street from DCI Shelby and less than three minutes (5 miles) to DCI South and approximately 15 minutes (11 miles) to DCI Boiling Springs.

One of the medical social worker's listed addresses is Oakland, California and her currently place of employment is El Camino Hospital. No letter or other documentation is included that states she is planning to relocate to North Carolina to work for BMA locally. This is problematic in that CMS requirements dictate that complete psychosocial assessments must be done within thirty days of a patient's admission to the clinic. Clearly this assessment will be difficult to accomplish on a routine basis if the social worker lives in California. Further, none of the three named social workers listed in the BMA application are licensed in NC, according to the North Carolina Social Worker Board website. www.ncswboard.org While MSW licensure is not a state requirement, a higher standard of care such as provided by DCI requires that all the social workers be licensed.

On a comparative basis, BMA's staffing is also inferior to DCI's. In order to compare two projects that propose to develop 10 dialysis stations, DCI compared BMA staffing proposed in its current project to the DCI South project, DCI's most recent previously approved project proposing to develop ten dialysis stations. As shown in the tables below, DCI proposed one more staff person on the Monday/Wednesday/Friday treatment days than BMA.

DCI South Proposed Direct Care Staff – Table VII.10 (Project ID# C-7831-07)

	Times (e.g. 7A -12N)	*Sun*	*Mon*	*Tues*	*Wed*	*Thur*	*Fri*	*Sat*
Morning	6:15A-11:15A	0	4	3	4	3	4	3
Afternoon	11:30A-4:30P	0	4	3	4	3	4	3
Evening	NA	0	0	0	0	0	0	0

Proposed BMA Shelby Direct Care Staff – Table VII.10 (page 79)

	Times (e.g. 7A -12N)	*Sun*	*Mon*	*Tues*	*Wed*	*Thur*	*Fri*	*Sat*
Morning	7:00 AM–12:00 PM	0	3	3	3	3	3	3
Afternoon	12:00 PM–5:00 PM	0	3	3	3	3	3	3
Evening	NA							

A further comparison of the proposed staffing tables (VII.1) from the two applications indicates that the DCI South project, while proposing the same number of stations as the current BMA project, proposed 2.0 FTEs *more* than the BMA project. It is particularly noteworthy that the number of RNs proposed by DCI South was *twice* the number proposed by BMA.

	DCI South FTEs	*BMA Shelby FTEs*
RNs	3.0	1.50
Techs	4.0	3.50
Total Direct Care	**7.0**	**5.0**

Thus, DCI is a more effective alternative when considering staffing, including total direct care staff as well as RN's.

Due to these deficiencies, the BMA application should be found non-conforming with Criteria 7 and 8, and should be found to be a less effective alternative in the comparative analysis.

BMA's proposal fails to meet the requirements of the ESRD rules

BMA's application does not adequately address several issues addressed by the criteria and standards for ESRD facilities. The issue with each of these rules is shown below.

10A NCAC 14C .2202 (b)

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.*

   BMA includes an agreement with Gaston Memorial Hospital but does not include an agreement with Cleveland Regional Medical Center, the hospital that is less than one mile from the proposed site. It is not reasonable that BMA would seek to-pass Cleveland Regional Medical Center to transport or refer patients to Gaston Memorial Hospital 23 miles from the proposed Kennedy Street site.

(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

(A) timeframe for initial assessment and evaluation of patients for transplantation,
(B) composition of the assessment/evaluation team at the transplant center,
(C) method for periodic re-evaluation,
(D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and
(E) signatures of the duly authorized persons representing the facilities and the agency providing the services.

In Exhibit 17, BMA includes an agreement drawn up as a BMA document but does not have any signatures from Carolinas Medical Center, although page 29 of the application states Exhibit 17 includes an executed transplant agreement. The unsigned agreement does not include a timeframe for initial assessment and evaluation, the composition of the evaluation team, a method for periodic re-evaluation, the criteria by which patient will be evaluated and periodically re-evaluate. Therefore, BMA is not conforming with this rule.

(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

BMA states that the sites are available for acquisition and indicates that a letter is included in Exhibit 30 which verifies the availability of the Kennedy Street site. However, Exhibit 30 does not contain a letter or any verifiable documentation that the site is available for development by BMA.

Based on these factors, BMA should be found non-conforming with these rules, as well as Criterion 3, and should be found to be a less effective alternative on a comparative basis.

Summary

In summary, DCI believes that its proposals, by the fact that they propose two locations, demonstrate superior alternatives to BMA's application. BMA's application contains inconsistencies, unreasonable assumptions and a less effective proposal to meet the need in Cleveland County. Although DCI is the only provider of dialysis services *within* the county, DCI believes it is important to recognize that competition already exists. As BMA states in its application, it already treats Cleveland County patients at a number of its facilities. Cleveland County patients are also likely treated in other counties by non-BMA providers as well. As such, competition for Cleveland County patients already exists. Moreover, as explained in Section V.7 of DCI's application, competition for dialysis services has a favorable impact when patients are not being adequately served or when the service is of poor quality and a high quality, patient-focused competitor can stimulate the existing service to positively impact the cost effectiveness, quality and access to care being provided.

Conversely, when the existing provider is mindful of its patients' needs and continually assesses the need for additional stations or the need to relocate stations to another site to be more accessible to patients, competition is not as effective because a high quality service may become diluted or even compromised. Furthermore, when the existing provider has a higher quality standard of care than any of the competitors, competition is not in the best interest of the patients being served. As demonstrated by the high volume of support letters from the community, including physicians and other providers, the high quality of care provided by DCI is a well-established fact.

For example, DCI, Inc. and its 222 clinics around the country has one of the highest standards of dialysis care in the country as evidenced by the recent data report from the United States Renal Data System (URDS). URDS found that DCI clinics consistently rank at the top in many of the important ESRD categories related to outpatient dialysis care. Specifically, the data indicate that:

- DCI has lower mortality rates than other providers;
- DCI has lower hospitalization rates than other providers;
- DCI is most consistent at meeting target hemoglobin levels;
- DCI is best at maintaining hemoglobin levels for three months or more;
- DCI patients are staying at hemoglobin levels longer than patients with other providers;
- DCI has a higher percentage of patients in their target hemoglobin range of 10-12 grams/deciliter;

- DCI has fewer patient likely to exceed hemoglobin levels of 12, 13, 14; and,
- DCI is the national provider with the lowest monthly cost to CMS at $1,366 per patient per month compared to a national average of $1,425 per patient per month.

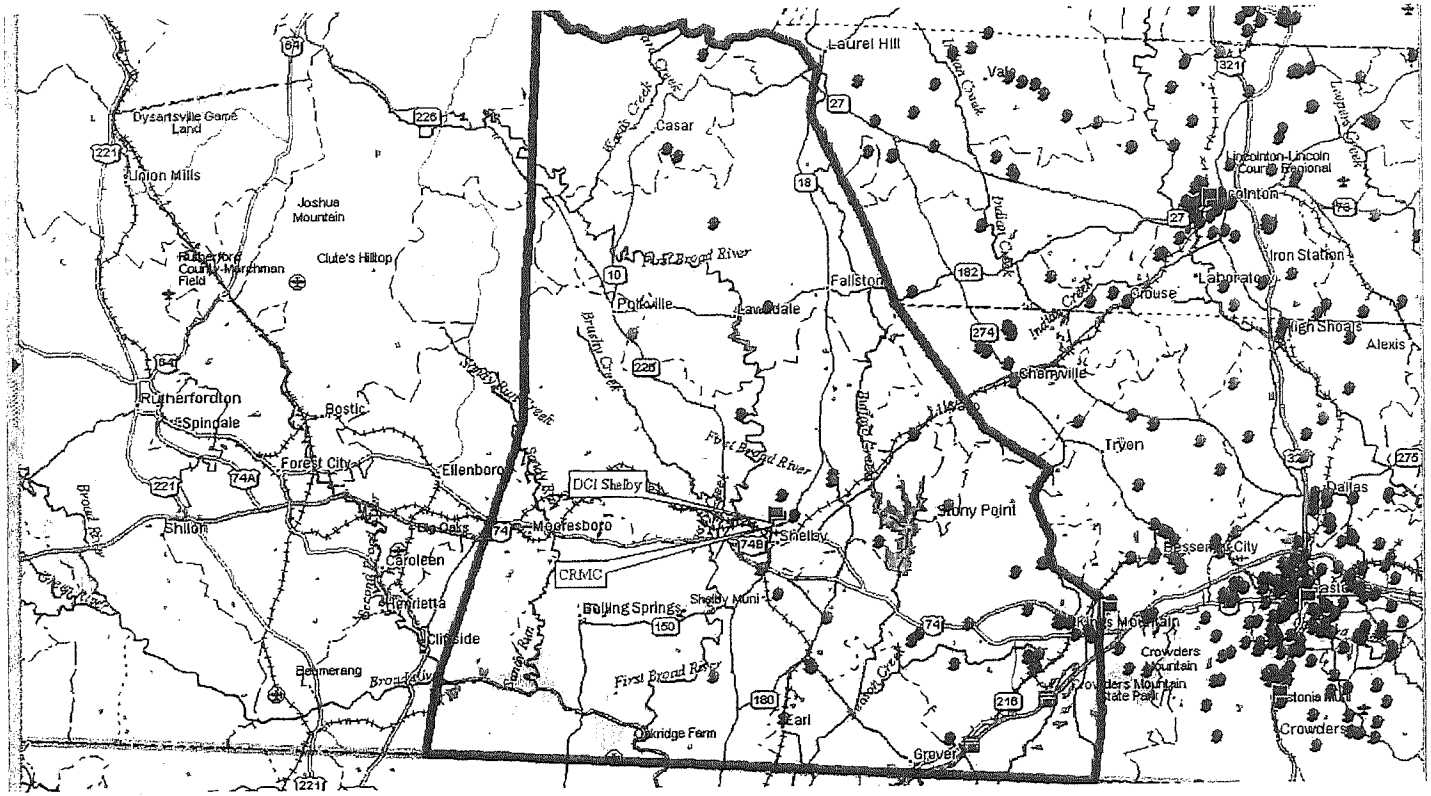
The fact that DCI continually monitors the need for additional stations in the Cleveland County area as demonstrated by the CON applications DCI submitted in 2004 (addition of five stations at DCI Shelby), 2005 (relocation of ten stations from DCI Shelby to a new facility in Boiling Springs and the addition of two stations at DCI Shelby), 2007 (relocation of ten stations from DCI Shelby to a new facility, DCI South), 2009 (addition of two stations at DCI Kings Mountain) indicates DCI's awareness of patient need and its willingness to use its resources to develop additional stations and relocate and establish clinics closer to the patients being served.

Further, as documented in the URDS report, DCI has the lowest monthly cost to CMS at $1,366 per patient per month compared to a national average of $1,425 per patient per month. When a provider can keep its costs low while continuing to provide an exceptionally high quality of care, it becomes the provider of choice for referrers, vendors, but especially for patients who are the beneficiaries of the high quality care. Moreover, with the additional stations as proposed by DCI Shelby, the dialysis center can improve access to its services, particularly for those patients who have higher co-morbidities and require a higher level of care than other dialysis patients. DCI has a reputation for higher staffing levels, more intense educational programs for patients and staff, higher standards of water purification and the processes for cleaning the artificial kidneys for reuse. Certainly, the mission of the organization -to exist solely for the benefit of ESRD patients - impacts the operations of all its 222 clinics throughout the country, and particularly those that operate in North Carolina.

Finally, DCI provides a higher quality dialysis service, has the lowest costs per patient while maintaining lower mortality rates, lower hospitalizations and better hemoglobin levels than its competitors. It is difficult to understand how the introduction of a competitor into the Cleveland County market would improve costs, quality or access to the existing dialysis services that are already documented by URDS as being one of the best in the nation. Particularly given the fact that BMA proposes inferior staffing, would not expand access to the growing number of patients already seeking ESRD treatment within Cleveland County, and is deficient in a number of areas as outlined above, DCI believes that its applications clearly represent the most effective alternative in this review.

Attachment 1

FMC Cleveland County
Exhibit 27, Map 1



FMC Cleveland County
Exhibit 27, Map 2