



December 30, 2020

Ms. Ena Lightbourne, Project Analyst  
Certificate of Need Section  
Division of Health Service Regulation  
North Carolina Department of Health and Human Services  
809 Ruggles Drive  
Raleigh, NC 27603

**RE: Total Renal Care of North Carolina, LLC'S Public Written Comments on a CON Application Filed by Bio-Medical Applications of North Carolina, Inc.**

Project ID#: B-11997-20  
Facility: FKC French Broad River Home Dialysis  
Project Description: Develop a new dialysis facility dedicated to providing home peritoneal dialysis training and support services  
County: Buncombe  
FID#: 200891

Dear Ms. Lightbourne:

Total Renal Care of North Carolina, LLC (TRC or DaVita) submits the following written comments on the CON Application submitted by Bio-Medical Applications of North Carolina, Inc. (BMA) to develop a new dialysis facility in Asheville to provide home peritoneal dialysis (PD) training and support services (Project ID# B-11997-20).

TRC submits these comments in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to address the representations in the BMA application.

BMA's utilization projections are unreasonable and inadequately supported, thus rendering BMA's application non-conforming with at least the review criteria at N.C. Gen. Stat. § 131E-183(a)(3), (a)(4), (a)(5), and (a)(6) (Criteria 3, 4, 5, 6).

1. Criterion (3) requires an applicant to identify the population to be served by the proposed project and demonstrate the need that this population has for the services proposed. The proposed project plans to serve home peritoneal dialysis (PD) patients residing in the tri-county area of Buncombe, Haywood and Henderson Counties. On page 22 of the application, BMA states that it "has filed this application in part to meet the needs of dialysis patients who have Humana Inc., health insurance."

In Section C, page 42, BMA explains why it believes the population projected to utilize the proposed services needs the proposed services:

*"Approval of this application will allow BMA to provide home peritoneal dialysis training and support services for the Humana patient population who dialyze at home using peritoneal dialysis. The alternative is not patient focused: patients who*

*desire to retain their Humana insurance must either travel to the nearest BMA facility, or contend with out of network care by another provider. The only other option these patients would have would be to discontinue their Humana insurance and change to another insurance carrier. Patients should not be forced to make such choices when reasonable alternatives are available.”*

Humana patients presently served by DaVita in Buncombe, Haywood and Henderson Counties receive in-network care. DaVita recently renewed its contract with Humana and will continue to be a participating provider in Humana’s network on January 1, 2021 and going forward. This applies to all Humana members, including those with Medicare Advantage, commercial and managed Medicaid coverage in all states. The agreement also includes a national value-based partnership to deliver integrated kidney care to Humana members treating in our centers. So the alternative presented by BMA -- that the current Humana patients in the tri-county area that BMA has identified will be **forced** to choose between being out of network with their current provider or to change to another insurance carrier -- is not based in fact.

In Section C, pages 33-34, BMA provides the assumptions used to project its patient origin. The applicant’s assumptions are not credible, reasonable nor adequately supported:

*2. BMA assumes the patients who have chosen Humana as their insurance would prefer to retain Humana as their insurance.*

*3. BMA assumes the four Humana PD patients will receive their care through the nearest BMA facility in Morganton, Burke County until the new FKC French Broad River Home facility is certified.*

...

*6. BMA assumes the starting census for this project will be comprised of four PD patients who have Humana health insurance.*

BMA provides no factual basis for the analyst to accept BMA’s assertion that all of the patients included in its starting census have **no choice** but to change dialysis providers and travel more than 60 miles through the mountains of western North Carolina in order to retain their Humana insurance.

BMA fails to demonstrate the need that this population, the Humana patients presently served by DaVita, has for the services proposed. They are not at risk of being out-of-network with their current provider as BMA falsely asserts. Moreover, BMA’s projected utilization is clearly not based on credible or reasonable assumptions. Given that BMA provides no basis for its assumptions regarding the Humana patients identified, the facility would have to begin with zero patients on December 31, 2021. This would make BMA’s current projections for the ending census for OY1 and OY2 unrealistic. The application should be found non-conforming to Criterion (3).

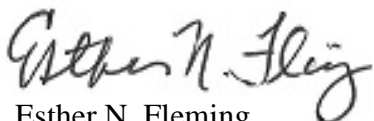
If the utilization is not based on reasonable assumptions, the project’s financials must also be found to be unreliable, and BMA’s application is not the most effective alternative. The application should also be found non-conforming to Criteria (4) and (5).

2. Criterion (5) requires an applicant to demonstrate financial feasibility of its proposal, based upon reasonable projections of the costs of and charges for providing the proposed services. Given that the assumptions used by the applicant in preparation of the pro forma financial statements are not reasonable nor adequately supported, as noted in TRC's discussion above regarding BMA's projected utilization, BMA fails to demonstrate the financial feasibility of the proposal. BMA cannot support the projected treatment volumes, which underlie the applicant's projected charges, since it provides no credible basis for including the Humana patients in its starting census. In Form F.2, the applicant does not project that revenues will exceed operating expenses in the first operating year of the project even with projected treatment volumes based on BMA's unreasonably overstated utilization. When the analyst excludes the four Humana patients that BMA provides no factual basis for including in its beginning census, it is impossible for the analyst to determine that a much lower utilization than what BMA projects will result in revenues that exceed operating expenses in *either* of the first two operating years. The application should be found non-conforming to Criterion (5).
  
3. Criterion (6) requires an applicant to demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities. Although this project does not include any dialysis stations, BMA does not adequately demonstrate that the proposed new dialysis facility is needed in addition to the existing dialysis facility in the service area which already provides home PD training and support services to the Humana patients BMA identifies. BMA claims throughout its application that Humana patients will not be able to receive in-network care with their current provider and therefore have a need for the proposed project. However, the proposed project unnecessarily duplicates the services that exist for Humana patients currently served by Biltmore Home Training in Buncombe County. Despite BMA's claims, patients with Humana insurance do not face being forced to decide between receiving out-of-network care or changing their insurance carrier in order to continue their home PD training and support with their current provider. The application should be found non-conforming to Criterion (6).

As a result of the foregoing, BMA's application fails to conform with multiple CON review criteria, including at least Criteria 3, 4, 5 and 6. Upon further review, TRC may determine that additional non-conformities, inconsistencies or errors exist in the BMA application.

You can contact me at 704-323-8384 if you have any questions or need more information.

Sincerely,



Esther N. Fleming  
Director, Healthcare Planning