



September 3, 2019

Ms. Julie Faenza, 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 Bio-Medical Applications of North Carolina Inc.'s CON Application

Project ID#: J-11739-19
Facility: FKC West Johnston
Project Description: Relocate 4 dialysis stations from Southwest Wake County Dialysis (Wake County) to Fresenius Kidney Care West Johnston (Johnston county) pursuant to Policy ESRD-2
County: Johnston
FID#: 170323

Dear Ms. Faenza:

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 relocate four (4) dialysis stations from Southwest Wake County Dialysis to FKC West Johnston (Project ID# J-11739).

The July 2019 Semiannual Dialysis Report (SDR) indicates that there is a projected 12 station deficit in Johnston County. TRC and BMA each submitted CON applications pursuant to Policy ESRD-2 for the August 1, 2019 review period, seeking a combined total of 14 dialysis stations. TRC's application proposed to develop a new ten (10) station facility (Project ID# J-11743-19) while BMA's application proposed to relocate four (4) stations from its facility in Wake County to its FKC West Johnston facility. TRC submits these comments in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to address the representations in the application submitted by BMA, including a comparative analysis and discussion as to whether BMA's application conforms with the statutory and regulatory review criteria in N.C. Gen. Stat. §131E-183(a) and (b).

General Comments

BMA's application should not be approved as proposed. BMA's application contains numerous errors, overstatements, and inconsistencies as well as insufficient responses to the Certificate of Need application form. The information in BMA's application as submitted renders BMA's application non-conforming to the applicable statutory Review Criteria and specific regulatory criteria and performance standards. TRC has grouped the errors, overstatements, inconsistencies, and insufficiencies by Criterion, each of which demonstrates BMA's nonconformity with the CON Review Criteria.

The primary goal of BMA's application is to prevent a new provider from entering Johnston County rather than satisfying the need for 12 stations to serve End Stage Renal Disease patients who need treatment.

REVIEW CRITERIA

BMA should be found non-conforming to Criterion (3)

The BMA application is nonconforming with Criterion (3). 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. BMA has failed to demonstrate the need for its proposed project because its utilization projections are not supported. BMA bases its utilization projections, in part, on fourteen (14) purported new patients who did not sign letters of support for its original West Johnston Project (Project ID# J-11435-17), but who have signed letters of support for BMA's current proposal (Project ID# J-11739-19).

On page 16 of its application, BMA states:

"BMA has identified 14 additional patients who did not sign letters of support for the original CON application for FKC West Johnston."

It reemphasizes this point on page 19:

"However, since approval of the FKC West Johnston CON application, Project ID# J-11435-17, the number of dialysis patients residing near the proposed facility has increased, BMA has identified 14 new dialysis patients, who have signed letters of support for this proposal."

It reemphasizes this point again on page 28:

"Each of these patients was not a dialysis patient at the time of the original application for FKC West Johnson and therefore could not have signed a letter of support for the proposal."

However, four of the 2019 letters appear to be from patients who signed letters for BMA's 2017 application, Project ID# J-11435-17 (see attachment 1). These duplicative letters of support result in overstated projections and call into question BMA's credibility. The duplicative letters of support should make the analyst question whether the in-center utilization is based on reasonable and adequately supported assumptions regarding projected growth at FKC West Johnston.

BMA should be found non-conforming to Criterion (4)

The BMA application is nonconforming with Criterion (4). Criterion (4) requires an applicant to demonstrate that its proposed project is the least costly or most effective alternative. BMA's application fails to demonstrate that its proposed project is the least costly or most effective alternative.

BMA discusses three alternatives related to serving the needs of patients in the area that it considered to prior to the submission of this application: (1) maintaining the status quo, (2) relocating more than 4 stations, and (3) relocating fewer than 4 stations.

BMA, the only ESRD provider in Johnston County, has 3 operational facilities in Johnston County. At the time BMA submitted its application, one of BMA's three existing facilities, FMC Four Oaks, was operating at 73.86% utilization. Yet BMA did not present the alternative of relocating stations from FMC Four Oaks to FKC West Johnston. The Agency previously has denied CON applications where applicants did not explain why they did not consider relocating stations from an underutilized facility in the same county¹.

Additionally in its response in Section C, question 5(a) "Explain why the facility or stations need to be relocated", BMA states:

"Relocation of four dialysis stations as proposed by this application will serve to reduce the deficit of stations in Johnston County."

However, BMA also notes on page 17 that:

"Johnston Dialysis facility qualifies to apply for one station pursuant to the Facility Need methodology in the July 2019 SDR, and FMC Stalling Station Dialysis facility qualifies to apply for two stations pursuant to the Facility Need methodology in the July 2019 SDR. BMA will file to add stations to those facilities in September 2019, for the CON Review which commences on October 1, 2019."

There is no pressing need to relocate the stations from Wake County into Johnston County since BMA's proposed project isn't projected to be complete until December 2020 and any stations approved during the October 1, 2019 review period would certainly be available to current patients much sooner than the stations proposed by BMA's application.

BMA essentially acknowledges above, and as referenced in TRC's discussion regarding the deficiencies in BMA's application both with regard to this Criterion (4) and with regard to Criteria (18a), that BMA's proposed project is not the only alternative for reducing the deficit of stations in Johnston County or meeting the needs of patients treating in operational facilities, but instead it is an effort to prevent a new provider - DaVita - from developing a new facility in Johnston County.

BMA should be found non-conforming to Criteria (5) and (7)

The BMA application is nonconforming with Criteria (5) and (7). Criterion (7) requires an applicant to show evidence of adequate staffing for its proposed project. BMA's application fails to demonstrate the financial feasibility of its proposed project since its staffing projections are inadequate.

¹ An example is Southern Pines Dialysis, Project ID# H-11085-15

The applicant proposes to increase the number of stations at FKC West Johnston from 10 to 14, but indicates that the projected staffing for the facility has not changed. This is surprising since, as reflected in the table below, in its FMC Regal Oaks application (Project ID# F-10369-15) to develop a 12-station facility in Mecklenburg County, BMA's staffing is greater than its proposed 14-station project proposed in its current application. It is unreasonable to expect that the staffing BMA proposed for its original 10 station facility in Project ID# J-11435-17 (serving a projected 34 patients in OY1), would be adequate for the 14-stations it now proposes to serve through this project (serving a projected 45 patients in OY1). For this reason, BMA should be found non-conforming to Criterion (7).

	# of FTEs OY1 FKC Johnston Proj ID# J-11435-17 (10-stations)	# of FTEs OY1 FKC Johnston Proj ID# J-11739-19 (14-stations)	# of FTEs OY1 FMC Regal Oaks Proj ID# F-10369-15 (12-stations)
RN	1.5	1.5	3.50
PCT	4.0	4.00	6.50
Administrator/Clinic Mgr	1.00	1.00	1.00
Dietician	.40	.40	.70
Social Worker	.40	.40	.70
Chief Tech	.15	.15	.20
Equipment Tech	.60	.60	.80
In-Service	.15	.15	.20

BMA's inadequate staffing projections result in underreported operating costs. Review Criterion (5) requires the applicant to provide evidence of the financial feasibility of its proposal, specifically that it is *"based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service."* With underreported operating costs, BMA's financial and operational projections are unreasonable and unsupported and BMA should therefore be non-conforming to Criterion (5).

BMA should be found non-conforming to Criterion (18a)

BMA's application is nonconforming with Criterion (18a). Criterion (18a) requires an applicant to demonstrate the expected effects of its proposed project on competition in the proposed service area. BMA's application does not provide the proposed service area with enhanced competition.

BMA states on page 59 of its application:

"The applicant does not expect this proposal to have any effect on the competitive climate in Johnston County"

This statement is inconsistent with statements BMA makes in other parts of its application. BMA is currently the only provider in Johnston County. As evidenced by BMA's own admission, the expressed purpose of BMA's application is to negatively impact the competitive climate in Johnston County by preventing a new alternative provider from entering the county - specifically

DaVita - so as to preserve its monopoly on serving ESRD patients in Johnston County. BMA makes this very clear when it states on pages 59-60 of its application:

"BMA also notes that with a 12 station deficit as published in the July 2019 SDR, it is possible that another provider may apply to transfer stations into Johnston County. The only provider with surplus stations in a contiguous county would of course be DaVita Dialysis.

Approval of this application to relocate four stations into FKC West Johnston will necessarily result in the denial of an application by DaVita Dialysis. The station deficit is 12 stations. If BMA is approved to relocate four stations into FKC West Johnston, then the deficit is reduced to eight stations.

The NC State Medical Facilities Plan has determined that the minimum dialysis facility size is 10 stations. Approval of BMA for all four stations will remove the possibility of approval of an application by DaVita because the deficit would be reduced to less than 10 stations."

Clearly, the approval of BMA's proposed project will not have a favorable impact on cost effectiveness, quality or access.

In an attempt to explain why its proposal makes more sense than new competition entering Johnston County, BMA states on page 60 of its application that:

"BMA is seeking to redistribute existing and approved health services in a manner that doesn't over saturate the market with dialysis stations."

This statement is also inconsistent with statements BMA makes in other parts of its application. There is a 12-station deficit in Johnston County. How is possible to "over saturate a market" with a proposed project that isn't projected to meet the needs of the current and future ESRD patients in Johnston County? BMA's application only proposes to satisfy one-third of the 12-station deficit in Johnston County, and fails to address the remaining need that its proposed project purports to address.

BMA further attempts to demonstrate conformity with this Criterion by explaining why the approval of a DaVita facility in Johnston County would have an unfavorable impact on cost effectiveness, quality and access to the proposed services. On page 61, BMA states:

"Another facility in the county would stress the pool of qualified nurses, and further exacerbate the nursing shortage. As the nursing shortage expands, staff salaries will increase as providers seek to attract viable candidates for employment."

Yet, BMA makes no mention of these "challenges" in its discussion of filling vacant positions on page 42 of its application. BMA anticipates no significant difficulties in filling staff positions for the expansion proposed in BMA's FKC West Johnston undeveloped project or for the other undeveloped project it has in Johnston County, FKC Selma (Project ID# J-11372-17). Clearly BMA raises this point only in an attempt to defend against a new provider entering the county.

For these reasons, BMA should be found non-conforming with Criterion (18a).

COMPARATIVE FACTORS

Access to Alternative Providers

This is the most important comparative factor in this competitive review. The BMA application is not the most effective alternative on the comparative factor of new alternative provider. As noted in TRC's discussion regarding BMA seeking to maintain its monopoly in Johnston County, found in Criterion (18a) and incorporated herein by reference, BMA concedes that the 12-station deficit of stations presents an opportunity for an additional, alternative provider to enter Johnston County.

As discussed throughout these comments, BMA is a current and the only provider of ESRD services in Johnston County. In fact, BMA currently operates three facilities in Johnston County. On the other hand, the TRC application offers ESRD patients a choice of a new provider of ESRD services in Johnston County. Therefore, the TRC application is the most effective alternative on this comparative factor.

Access by Underserved Groups

The BMA application is not the most effective alternative on the comparative factor of access by underserved groups. There are inconsistent statements throughout BMA's application concerning the access it provides to underserved groups.

BMA does not include its policy on Charity Care or reduced cost care in response to Section L question 4(b). However, on its Form F.2 Income Statement, BMA states:

"The applicant does not collect data on patients receiving charity care. Therefore, the applicant cannot quantify the number of patients receiving charity care each year. The applicant generally assumes that all patients desire and plan to attend to legitimate medical bills. However, in some cases, patients do not have sufficient financial resources to attend to all medical bills; this results in unpaid or un-collectable accounts. The applicant allocates these un-collectables to a "Bad Debt" account."

BMA goes on to say in its Form F.2 Income Statement Assumptions:

"The Charity Care line is actually facility contributions to the American Kidney Fund."

These two statements are inconsistent with one another. An additional inconsistency is the inclusion of a separate line item for "Other: Medicare/ Commercial" when the CON application requests that the Medicare line include any managed care plans. These inconsistent statements make it unclear what then is represented in BMA's payor mix. It is therefore not possible to conduct an "apples to apples" comparison of TRC and BMA's applications for this comparative factor, making the result of this analysis inconclusive.

Revenues and Operating Costs

The BMA application is not the most effective alternative on this comparative factor. The discussions regarding utilization found in Criterion (3), staffing projections found in Criterion (5) and operating costs found in Criterion (7) are incorporated herein by reference. With revenue based on BMA's unreasonable and inadequately supported projected utilization and operating costs based on BMA's inadequate staffing projections, it is not possible to accurately compare BMA and TRC's applications. With regard to this comparative factor, the result of this analysis is inconclusive.

Staffing: Availability of Staff

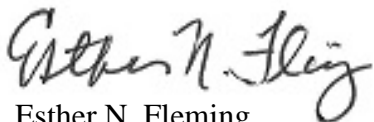
The BMA application is not the most effective alternative on this comparative factor. The discussion regarding BMA's inadequate staffing found in Criterion (7) is incorporated herein by reference. TRC projects a sufficient number of direct care staff for the projected number of patients to be served in OY2. The TRC application is the most effective alternative on this comparative factor.

For the reasons discussed in the Comparative Analysis comments, the TRC application is the most effective alternative on the Comparative Review.

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

Attachment 1: Duplicate patient letters

DATE: June 6, 2019

Ms. Lisa Pittman, Assistant Chief
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Dear Ms. Pittman:

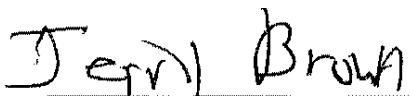
I am a dialysis patient receiving my dialysis treatments at Johnston dialysis facility. My residence zip code is 27520. I live in Johnston County.

I understand that Bio-Medical Applications of North Carolina is submitting an application for a Certificate of Need to relocate four dialysis stations from its Southwest Wake County Dialysis facility in Wake County, to the new Fresenius Kidney Care West Johnston dialysis facility in Johnston County. I understand FKC West Johnston will have 14 dialysis stations upon completion of this project. I enthusiastically support relocation of four additional stations to the Fresenius Kidney Care West Johnston dialysis facility.

Patients on dialysis have many hardships, especially arranging transportation three days per week. The location of the new Fresenius Kidney Care West Johnston facility is closer to my residence location and would be more convenient for me than my current dialysis facility. Dialyzing at the new location would mean less time involved in transportation and more time for me, and my needs.

Continuity of my care is very important to me. I understand that the Fresenius Kidney Care West Johnston facility will be operated in the same manner as my current facility. I also understand that my nephrology physician will be admitting / rounding on dialysis patients at the facility. Since the quality of my care would not change, I would be willing to consider transferring to the Fresenius Kidney Care West Johnston dialysis facility.

I am aware that this letter will be used as support for the Bio-Medical Applications of North Carolina application for Certificate of Need. By my signature below, I consent to my name being associated with this application. I further understand that no other Protected Health Information, PHI, regarding me, my diagnosis or treatment is released as a part of this application. I wish Bio-Medical Applications of North Carolina every success in this effort.



Jerry Brown

Jerry Brown

DATE: November 3, 2017

Ms. Martha Frisone, Chief
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Dear Ms. Frisone:

I am a dialysis patient receiving my dialysis treatments at Johnston Dialysis Center. My residence zip code is 27520, and I live in Johnston County.

I understand that Bio-Medical Applications of North Carolina is submitting an application for a Certificate of Need to develop a new 10 station dialysis facility by relocating existing dialysis stations to a new location near the Highway 42 and I-40 interchange in Johnston County, NC. I enthusiastically support development of the new Fresenius Kidney Care West Johnston dialysis facility.

Patients on dialysis have many hardships, especially arranging transportation three days per week. The location of the proposed new facility is closer to my residence location and would be more convenient for me than my current dialysis facility. Dialyzing at the new location would mean less time involved in transportation and more time for me, and my needs.

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Jerry R Brown
(Patient Signature)

DATE: June 6, 2019

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Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

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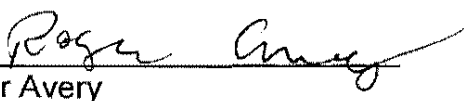
I am a dialysis patient receiving my dialysis treatments at Johnston dialysis facility. My residence zip code is 27520. I live in Johnston County.

I understand that Bio-Medical Applications of North Carolina is submitting an application for a Certificate of Need to relocate four dialysis stations from its Southwest Wake County Dialysis facility in Wake County, to the new Fresenius Kidney Care West Johnston dialysis facility in Johnston County. I understand FKC West Johnston will have 14 dialysis stations upon completion of this project. I enthusiastically support relocation of four additional stations to the Fresenius Kidney Care West Johnston dialysis facility.

Patients on dialysis have many hardships, especially arranging transportation three days per week. The location of the new Fresenius Kidney Care West Johnston facility is closer to my residence location and would be more convenient for me than my current dialysis facility. Dialyzing at the new location would mean less time involved in transportation and more time for me, and my needs.

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Roger Avery

Roger Avery

DATE: November 3, 2017

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Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

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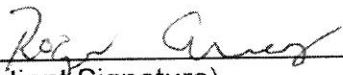
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Continuity of my care is very important to me. I understand that the Fresenius Kidney Care West Johnston facility will be operated in the same manner as my current facility. I also understand that my nephrology physician will be admitting / rounding on dialysis patients at the facility. Since the quality of my care would not change, I would be willing to consider transferring to the Fresenius Kidney Care West Johnston dialysis facility.

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(Patient Signature)

DATE: June 19, 2019

Ms. Lisa Pittman, Assistant Chief
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Dear Ms. Pittman:

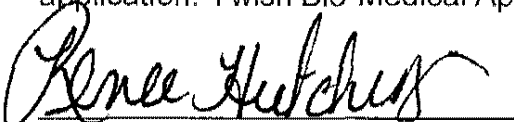
I am a dialysis patient receiving my dialysis treatments at Stallings Station Dialysis facility. My residence zip code is 27592 I live in Johnston County.

I understand that Bio-Medical Applications of North Carolina is submitting an application for a Certificate of Need to relocate four dialysis stations from its Southwest Wake County Dialysis facility in Wake County, to the new Fresenius Kidney Care West Johnston dialysis facility in Johnston County. I understand FKC West Johnston will have 14 dialysis stations upon completion of this project. I enthusiastically support relocation of four additional stations to the Fresenius Kidney Care West Johnston dialysis facility.

Patients on dialysis have many hardships, especially arranging transportation three days per week. The location of the new Fresenius Kidney Care West Johnston facility is closer to my residence location and would be more convenient for me than my current dialysis facility. Dialyzing at the new location would mean less time involved in transportation and more time for me, and my needs.

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Patient

DATE: 11/2/17

Ms. Martha Frisone, Chief
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Dear Ms. Frisone:

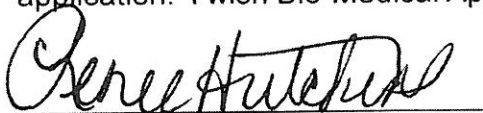
I am a dialysis patient receiving my dialysis treatments at BMA of Fuquay Varina Kidney Center. My residence zip code is 27592, and I live in Johnston County.

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809 Ruggles Drive
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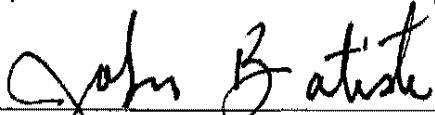
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Patient

DATE: 11-3-2017

Ms. Martha Frisone, Chief
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Dear Ms. Frisone:

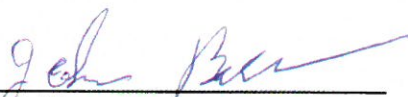
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