



March 2, 2020

Ms. Celia Inman, 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#: P-11840-20
Facility: FMC Sea Spray
Project Description: Relocate no more than 2 dialysis stations from Crystal Coast Dialysis Unit for home hemodialysis training and support services
County: Carteret
FID#: 120486

Dear Ms. Inman:

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 no more than 2 dialysis stations from Crystal Coast Dialysis Unit to FMC Sea Spray for home hemodialysis training and support services (Project ID# P-11840-20).

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 and facts relating to the service area, Carteret County.

In its application, BMA proposes to relocate two dialysis stations from Crystal Coast Dialysis Unit to FMC Sea Spray for those two stations to be used exclusively for home hemodialysis training and support services. (BMA application, p. 6). BMA further represents that FMC Sea Spray is a 10 station dialysis facility that "offers in-center dialysis as well as home training and support services for peritoneal dialysis and home hemodialysis." (BMA application, p. 6).

10A NCAC 14C .2203 is the performance standard applicable to ESRD facilities and services. 10A NCAC 14C .2203, amended temporarily effective February 1, 2020, provides in relevant part that an applicant who proposes to increase the number of dialysis stations in an existing facility must document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

For purposes of demonstrating need in its application, BMA suggests that the Agency should examine compliance with this performance standard in a two-pronged approach that separates the ten in-center stations from the two HHD stations because the HHD stations are exempt from

the performance standard by direction of the Director, DHSR, in a 2018 declaratory ruling. (BMA application, p. 24, 29). BMA represents that the 2018 “declaratory ruling directly related to proposal [*sic*] such as this one” where BMA “proposes to expand a facility” and “proposes that the two stations in question will exclusively serve home hemodialysis patients.” (BMA application, p. 24). In support of its position that its proposal to relocate two HHD stations to an existing facility is exempt from the performance standard, BMA quotes from the conclusion of the 2018 declaratory ruling, in which the Director stated “10A NCAC 14C .2203 should not apply to proposals to develop or expand a facility to exclusively serve home hemodialysis and home peritoneal patients.” (BMA application, p. 24). Using its suggested approach, BMA calculates that it proposes to serve 3.24 patients per station on the 10 in-center stations, and contends it does not need to satisfy any performance standard for the two HHD stations because these two stations are exempt from this performance standard, and as a result demonstrates need for its proposal. (BMA application, p. 29).

BMA’s application should be denied as nonconforming with Criteria (1) and (3) because BMA does not demonstrate the need required by the performance standard promulgated in 10A NCAC 14C .2203.

Although BMA asserts it is exempt from the performance standard in this case, it is evident from the content of the declaratory ruling itself that the only applications BMA sought to exclude from the performance standard were applications proposing to establish new dialysis facilities “to exclusively serve home hemodialysis and home peritoneal patients by relocating existing dialysis stations”. (Attachment 1, p. 3). The 2018 Declaratory Ruling is attached to TRC’s written comments as Attachment 1. Furthermore, the conclusion of the 2018 declaratory ruling specifically states that “10A NCAC 14C .2203 should not apply to proposals to develop or expand a facility to exclusively serve home hemodialysis and home peritoneal patients.” (BMA application, p. 24 and Attachment 1, p. 5). (emphasis added). The Director’s conclusion, read in the context of the entire Declaratory Ruling, makes clear that the only ESRD proposals to which the performance standard in 10A NCAC 14C .2203 does not apply are those proposals involving solely home hemodialysis and PD facilities. Thus, the Declaratory Ruling would not include dialysis facilities that are combination in-station and home hemodialysis and PD facilities.

Based on the representations in its application, FMC Sea Spray, the facility BMA proposes to expand, is **not** a facility exclusively serving home hemodialysis and PD patients. Instead, it is an in-center dialysis facility that also offers home training and support for HHD and PD patients. As the applicant notes on page 6 of its application in its project description:

“FMC Sea Spray is a 10 station dialysis facility, and offers in-center dialysis as well as home training and support services for peritoneal dialysis and home hemodialysis.”

Because the FMC Sea Spray facility is not dedicated exclusively to serving HHD and PD patients, the 2018 declaratory ruling exemption from the performance standard promulgated 10A NCAC 14C.2203 does not apply to BMA’s proposed relocation of HHD stations to expand the FMC Sea Spray facility.

The Required State Agency Findings for Project ID# F-11638-18 further support this interpretation. Relying on this same declaratory ruling, in January 2019, the Agency approved

BMA's application to relocate a total of four stations from BMA Beatties Ford to facilities exclusively serving HHD and PD patients in Mecklenburg County, INS Huntersville and INS Charlotte. In the Agency Findings for Project ID# F-11638-18, the project analyst states (emphasis added):

*“On August 8, 2018, Fresenius Medical Care Holdings, Inc.(FMC) – the parent company of INS, as well as the parent company of other dialysis facility operators – requested a declaratory ruling from the Agency stating that the requirements of 10A NCAC 14C .2203 will not apply to **facilities exclusively serving PD and HH patients**. On October 10, 2018, the Agency issued the declaratory ruling FMC had asked for...” (p. 3)*

*“The applicant proposes to relocate two dialysis stations from BMA Beatties Ford to INS Huntersville for the purpose of expanding a facility exclusively serving HH and PD patients. The Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200, are not applicable to this review due to a declaratory ruling issued by the Agency on October 10, 2018, which exempts the Criteria and Standards from applying to proposals to develop or expand **facilities exclusively serving HH and PD patients**.”¹ (p.27)*

The Agency should interpret the 2018 declaratory ruling consistent with its January 2019 interpretation in Project ID# F-11638-18 and in accordance with the plain language of the conclusion of the 2018 declaratory ruling to find that the exemption from 10A NCAC 14C.2203 does not apply to BMA's proposal in its current application.

As stated on page 19 of the application, BMA is proposing the relocation of two dialysis stations *“to FMC Sea Spray for a total of 12 dialysis stations at FMC Sea Spray upon completion of this project”* so the analyst must include all 12 stations in the evaluation of the performance standard rather than using a two-pronged approach that conducts a separate analysis of in-center stations from HHD stations. A simple calculation shows that BMA suggested a two-pronged approach in its application because it could not meet the performance standard without doing so.

In a table on page 20 of the application, BMA projects that the facility will have 32.4 in-center patients at the end of OY1 and 34.9 in-center patients at the end of the OY2. Based on these projections, FMC Sea Spray will have 32.4 patients utilizing 12 certified stations or 2.70 patients per station, which does not satisfy the 2.80 patients per station required by the performance standard. The applicant, therefore, fails to demonstrate the need for the total number of dialysis stations in the proposal, and as a result should be found nonconforming with Criteria (1) and (3).

In addition, BMA's application as proposed raises questions and concerns about future health care planning given the Agency's prior decision in Project ID# F-11638-18. In that case, the Agency approved the relocation of four stations - two dialysis stations to INS Huntersville (Project ID# F-11638-18) and two dialysis stations to INS Charlotte (Project ID# F-11637-18).

¹ TRC disagrees with the Agency's finding to the extent the Agency asserts that the declaratory ruling exempts the Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 from applying to proposals to develop or expand facilities exclusively serving HH and PD patients because the declaratory ruling was clear that only 10A NCAC 14C .2203 was at issue in the declaratory ruling, not all Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 et seq.

These four stations, however, were last accounted for in Table B of the January 2019 Semiannual Dialysis Report (SDR). INS Huntersville and INS Charlotte, which are not ordinarily listed in Table B of the SDR because these facilities do not include in-center stations that are tracked within the inventory of dialysis stations in North Carolina, were included in Table B of the January 2019 SDR with the following note:

*“*** Application submitted 11/16/18 proposing the relocation of four stations from BMA Beatties Ford to INS Charlotte (2 stations) and INS Huntersville (2 stations) for home training only.”*

Since then, however, there has been no accounting for these four stations in Mecklenburg County. Neither Table B July 2019 SDR nor Table 9B of the 2020 State Medical Facilities Plan (SMFP) account for the INS Huntersville or the INS Charlotte facilities nor these four dialysis stations in Mecklenburg County. Therefore, a dialysis provider attempting to determine whether additional dialysis facilities or stations are needed in Mecklenburg County subsequent to July 2019 has an inaccurate picture of the actual inventory of existing dialysis stations in Mecklenburg County and the respective utilization rates of each facility. Although the SMFP is to be used by all providers a planning tool, providers cannot plan accurately since there are home hemodialysis stations that are not accounted for in the formal SMFP inventory.

BMA’s application, if approved, will present an even more serious concern from a planning and competition perspective since these two additional HHD stations, which are being added to an in-center facility, will not be accounted for within the SMFP Table 9B inventory of dialysis stations in Carteret County. Thus, in looking at the SMFP inventory, BMA’s Sea Spray Facility will appear to only have ten (10) stations when in reality it will have twelve (12) stations. Those two (2) additional stations, even if dedicated exclusively to home hemodialysis, should be accounted for in the SMFP since failure to do so provides an incomplete and inaccurate picture to both providers and the public of the dialysis station inventory and utilization on which any need is based. Moreover, should BMA decide at some point to convert these two home hemodialysis stations to in-center stations at FMC Sea Spray or relocate these two stations from FMC Sea Spray to another facility as in-center stations, that would affect the inventory in the SMFP, but as evidenced by the relocated stations in approved Project ID# F-11638-18, may not necessarily be reflected in the SMFP’s Table 9B inventory. As a result, BMA’s proposal leads to several concerns and questions concerning planning as it relates to relocated home hemodialysis stations, including whether relocated home hemodialysis stations: (1) will be accounted for in the SMFP; (2) can be converted back into in-center stations that will then be accounted for in Table 9B; (3) can be backfilled with in-center stations at the facility from which the home hemodialysis stations were relocated; and (4) can be collected over time and then converted to a new 10-station in-center facility once enough stations have been accumulated.

At least one of these questions and concerns is raised specifically by BMA’s statement on page 25 of the application where BMA explains that Crystal Coast Dialysis Unit qualifies to apply for up to eleven (11) additional stations, and that it is preparing an application for filing in March 2020 for the April 1 review “to replace the stations being relocated.” If its current application is approved using the exemption as BMA desires, BMA will be increasing the inventory of stations at FMC Sea Spray without demonstrating the need for such stations, and if its application to

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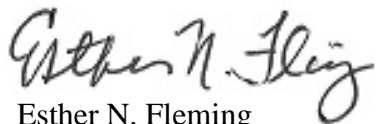
replace the stations being relocated is approved, will be further increasing the inventory of stations in Carteret County.

Given the questions and concerns raised by the BMA application to relocate two home hemodialysis stations to a 10-station in-center facility, TRC respectfully requests that the Agency determine that holding a public hearing on BMA's proposal is in the public interest and hold a public hearing within the timeframe permitted by N.C. Gen. Stat. § 131E-185(a1)(2).

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.

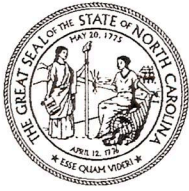
Sincerely,

A handwritten signature in black ink, appearing to read "Esther N. Fleming". The signature is written in a cursive, flowing style.

Esther N. Fleming
Director, Healthcare Planning

Attachment 1: October 10, 2018 Declaratory Ruling

cc: Fatimah Wilson, Team Leader, Certificate of Need Section
Martha Frisone, Chief, Healthcare Planning and Certificate of Need Section



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

October 10, 2018

CERTIFIED MAIL

Mr. Jim Swann
FRESENIUS KIDNEY CARE
3390 Dunn Road
Eastover, North Carolina 28312

RE: Declaratory Ruling by Fresenius Medical Care Holdings, Inc.
d/b/a Bio-Medical Applications of North Carolina, Inc.

Dear Mr. Swann:

I am enclosing a Declaratory Ruling that you requested. If questions arise, do not hesitate to let me know.

Sincerely,

Mark Payne

MP:peb

Enclosure

cc: Emery E. Milliken, Deputy Director
Martha Frisone, Chief, Healthcare Planning & Certificate of Need Section
Azzie Conley, Chief, Acute & Home Care Lic. & Cert. Section
Steve Lewis, Chief, Construction Section
June Ferrell, Special Deputy Attorney General, DOJ
Diana Barbry, Executive Assistant to the Director
Erin Glendening, Information Systems

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA**

**IN RE: REQUEST FOR DECLARATORY)
RULING BY FRESENIUS MEDICAL CARE) DECLARATORY RULING
HOLDINGS, INC. d/b/a BIO-MEDICAL)
APPLICATIONS OF NORTH CAROLINA, INC.)**

I, Mark Payne, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services (the “Department” or “Agency”), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statutes § 150B-4 and 10A N.C.A.C. 14A .0103, under the authority granted me by the Secretary of the Department of Health and Human Services.

On August 8, 2018, Fresenius Medical Care Holdings, Inc., d/b/a Bio-Medical Applications of North Carolina, Inc. (“BMA”), the owner and operator of end stage renal disease (“ESRD”) treatment facilities, requested a declaratory ruling as to the applicability of Chapter 131E, Article 9 (Certificate of Need Law) of the North Carolina General Statutes, and of the Department’s rules, to the facts described below. Specifically, BMA requests a determination that 10A NCAC 14C .2203 Performance Standards should not apply to proposals to develop dialysis stations dedicated exclusively to the provision of home hemodialysis training and support services. This ruling will be binding upon the Department and the entity requesting it as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by North Carolina General Statutes § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. Jim Swann, Director of Operations, Certificate of Need, for Fresenius Medical Care Holdings, Inc., has requested this ruling on behalf of BMA and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

There are three (3) methods or modalities for kidney dialysis: in-center, home hemodialysis, and home peritoneal dialysis. In-center patients report to the ESRD facility for dialysis while the other two modalities are performed in the patient's home. The home hemodialysis modality uses a machine or dialysis station similar to the ones used for in-center patients in the ESRD facility.

No person can develop a new dialysis station without first obtaining a certificate of need ("CON"). N.C. Gen. Stat. §§ 131E-178(a), -176(2), -(5), and -(16). In order to be approved for a CON, the applicant must demonstrate that its proposal is consistent with all applicable review criteria. N.C. Gen. Stat. § 131E-183(a). Pursuant to N.C. Gen. Stat. § 131E-183(b), the Department is authorized to adopt rules for review of particular types of applications that will be used in addition to the criteria contained in N.C. Gen. Stat. § 131E-183(a). In 1989, the Agency adopted rules for the review of dialysis applications. At present, there is only one such rule:

10A NCAC 14C .2203

PERFORMANCE STANDARDS

- (a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.
- (b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.
- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

ANALYSIS

10A NCAC 14C .2203 has not been amended since 2010. According to the January 2010 Semiannual Dialysis Report (“SDR”), as of June 30, 2009, there were a total of 13,607 dialysis patients utilizing North Carolina facilities. Of these, 12,261 were being dialyzed in a facility (90%) and 1,346 were dialyzing at home (10%).¹ The percentage of home dialysis patients varied considerably from county to county. For example, 41% of patients living in Currituck County dialyzed at home. Even today, there is no dialysis facility located in Currituck County. According to the July 2018 SDR, as of December 31, 2017, there were a total of 18,038 dialysis patients utilizing North Carolina facilities. Of these, 15,804 were being dialyzed in a facility (87.6%) and 2,234 were dialyzing at home (12.4%).² Therefore, while the total number of dialysis patients has increased by 24% since 2010, the number of dialysis patients dialyzing at home has increased by 66%.

Since 2008, the Agency has received three (3) applications proposing to establish a new dialysis facility to exclusively serve home hemodialysis and home peritoneal patients by relocating existing dialysis stations. The language of 10A NCAC 14C .2203 does not expressly limit itself to dialysis stations used by in-center patients, so the rule was applied during the review of all three applications. All three applications were denied because the applicant could not adequately demonstrate that dialysis stations utilized exclusively by home hemodialysis patients would serve 3.2 patients per station per week as required by 10A NCAC 14C .2203.

The assumptions regarding the capacity of dialysis stations used by in-center dialysis patients are:

- The facility will be open six (6) days per week.
- The facility will staff two (2) shifts per day.

¹ The January 2010 SDR does not break down the home patients into peritoneal and home hemodialysis.

² The July 2018 SDR does break down the home patients into peritoneal and home hemodialysis.

- Each patient receives three (3) treatments per week.

Based on these assumptions, a single station can serve four (4) in-center dialysis patients per week at 100% of capacity. The performance standard requires 80% capacity, or 3.2 patients per station per week. While hemodialysis patients are trained in the facility and are monitored periodically in the facility, the patient completes dialysis at home. The number of home hemodialysis patients that can be served by a single station in a week differs from the number of in-center dialysis patients that can be served in a week. At this time, however, the Agency does not have a standard for home hemodialysis utilization.

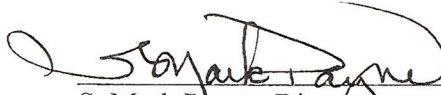
As part of the periodic review of rules process, 10A NCAC 14C .2203 was determined by the Agency to be necessary with substantive public interest. This means that the rule will need to be re-promulgated. The reason the rule was designated by the Agency as necessary with substantive public interest is the need to reword the existing subparts (a) and (b) so that it is clear that they apply only to proposals involving in-center dialysis stations and to add a new performance standard specifically for home hemodialysis stations.

If 10A NCAC 14C .2203 did not apply to proposals to develop or expand a facility to exclusively serve home hemodialysis and home peritoneal patients, the applicant would still be required to demonstrate that the proposal is consistent with all applicable statutory review criteria, which includes demonstrating the need the patients to be served would have for the proposed services and that the proposal would not result in an unnecessary duplication of existing or approved dialysis stations in the service area.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that 10A NCAC 14C .2203 should not apply to proposals to develop or expand a facility to exclusively serve home hemodialysis and home peritoneal patients.

This the 10th day of October, 2018.



S. Mark Payne, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I have this day served the foregoing Declaratory Ruling upon the PETITIONER by certified mail, return receipt requested, by causing a copy of same to be placed in the United States Mail, first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

Jim Swann
FRESENIUS KIDNEY CARE
3390 Dunn Road
Eastover, North Carolina 28312

This the 10th day of October, 2018.

Patricia Bryant
Patricia Bryant
Administrative Assistant
Division of Health Service Regulation