**TOPCATS Division**
2321 West Morehead Street
Charlotte, NC 28208

March 2, 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 FMS ENA Home, LLC**

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|---|---|
| Project ID#: | L-11836-20 |
| Facility: | Wilson Home Dialysis |
| Project Description: | Develop a new dialysis facility in Wilson to provide home peritoneal dialysis training and support services |
| County: | Hertford |
| FID#: | 200027 |

Dear Ms. Lightbourne:

Total Renal Care of North Carolina, LLC (TRC or DaVita) submits the following written comments on the CON Application submitted by FMS ENA Home, LLC (FMS), a joint venture between Bio-Medical Applications of North Carolina Inc. (BMA) and Eastern Nephrology Associates (ENA), to develop a new dialysis facility in Wilson to provide home peritoneal dialysis (PD) training and support services (Project ID# L-11836-20).

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

## I. FMS's Utilization Projections Are Unreasonable.

FMS's utilization projections are unreasonable, thus rendering FMS'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)(18a) (Criteria 3, 4, 5, and 18a).

Page 19 of the FMS application represents the following:

> "The applicant assumes that the ESRD patient population can achieve a home penetration of ***at least 25%.*** Indeed, there are already multiple counties across the state with home penetrations exceeding 20%."

(emphasis added).

FMS specifically compares its Wilson County situation to Buncombe County, because the two counties have somewhat similarly-sized patient populations. By cherry picking Buncombe

County's exceptional home penetration, FMS draws an incomplete picture and sets a faulty foundation for its growth assumptions.

DaVita includes two tables below, which place home penetration projections in perspective. The left table contains data from Table 9C of the 2020 State Medical Facilities Plan (SMFP) of counties similar in patient population size to Hertford (270 to 300 total patients). The table on the right reflects the rates of home penetration for Wilson County extracted from prior years' Semiannual Dialysis Reports (SDRs).

| County/ Multi-County Planning Area | 12.31.18 Total Patients | 12.31.18 Percent Home Patients |
|---|---|---|
| Buncombe | 272 | 23.9% |
| Catawba | 292 | 14.7% |
| Davidson | 291 | 19.9% |
| Harnett | 266 | 12.0% |
| Nash | 273 | 13.9% |
| New Hanover | 281 | 14.6% |
| Union | 274 | 8.8% |
| Wilson | 285 | 15.4% |

**Wilson County Data**

| SDR Version | Total # of Hertford Co ESRD Pts | # Home Pts | Percent Home |
|---|---|---|---|
| Jul 2016 SDR | 263 | 49 | 18.6% |
| Jul 2017 SDR | 276 | 53 | 19.2% |
| Jul 2018 SDR | 298 | 52 | 17.4% |
| Jul 2019 SDR | 285 | 44 | 15.4% |

As the table on the left illustrates, FMS's point of comparison - Buncombe County - is the only one in the group exceeding 20% home penetration. Additionally, the average rate of home penetration for this group of similar counties is 15.4%. Thus, FMS unreasonably seeks to rely on an aberration - Buncombe County - for its projections.

Further, FMS ignores the lack of growth among Wilson County home dialysis patients. As the table on the right above illustrates, the Wilson County home patient population has been stagnant, with recent declines.

Given the comparable county averages and the Wilson County trend line discussed above, FMS's projected 25% home penetration is not a reasonable assumption for Wilson County.

On page 21 of the application, FMS again states "that it is reasonable to project a home penetration of as much as 25%" because the applicant "has experienced significant growth in home PD patient populations after development of a similar facility in Tarboro, Edgecombe County." However, Edgecombe Home Dialysis was certified in October of 2017, and by the end of the facility's first operating year (2018), FMS concedes that Edgecombe County's home patient penetration was 14.6% - well below the 25% it expects to see in Wilson County by the proposed project's first operating year. The analyst must ask why this example serves as reasonable support for FMS's assumption on page 22 of the application: "Wilson Home Dialysis assumes that the home patient penetration of Wilson County will increase to a rate of 25% by December 31, 2021."

Additionally, FMS fails to shed any light on what portion of BMA's in-center population may have converted to home dialysis, contributing to the purported "significant growth in PD patient

populations" in Edgecombe County. BMA serves in-center patients at two facilities in Edgecombe County: BMA East Rocky Mount and FMC Tarboro. In order to achieve 25% home penetration, where 1 in 4 ESRD patients is receiving PD training and support, some of the growth it has achieved must come from the existing in-center population converting to PD. But BMA does not have an in-center dialysis program in Wilson County.

A more appropriate comparison would be with BMA's FMC Bladen Home Dialysis in Bladen County. In BMA's Bladen Home Dialysis application (Project ID #N-10153-13), BMA provided documentation of a physician referral base in Bladen County with Carolina Kidney Care, a group of eleven nephrologists who treated patients in Bladen County. At the time the application was submitted, the January 2013 SDR reported that 14 of 95 Bladen County patients (14.7%) were home patients. Like the proposed Wilson Home Dialysis, BMA did not have a dialysis facility in Bladen County when Bladen Home Dialysis opened in 2016. Below is a table that reflects the home patient census at the Bladen Home Dialysis, which BMA reports in its December 2019 ESRD Data Collection Form is no longer Medicare/Medicaid certified (effective September 30, 2019).

| SDR Version | FMC Bladen Home Dialysis - Patient Census |
|---|---|
| Jul 2016 SDR | 0 |
| Jul 2017 SDR | 3 |
| Jul 2018 SDR | 1 |
| Jul 2019 SDR | 0 |

As FMS and BMA are aware, not every patient who starts training on a home modality successfully transitions to dialyzing at home. In fact, as BMA has conceded in a recently submitted application, "There are also a significant number of patients who begin the journey for home hemodialysis and ultimately determine that another modality…is more appropriate, or, leave home hemodialysis for other reasons such as transplant or death." *See* BMA's INS Huntersville Application (Proj ID# F-11842-20). While this quote specifically refers to home hemodialysis, the same is true for PD and is clearly not accounted for in the example of Edgecombe Home Dialysis.

On page 57, the FMS application states that it "does not project to serve dialysis patients currently being served by another provider. The applicant does not forecast that any patients will change dialysis providers. Rather, projections of future patient populations are derived from the growth of the Wilson County ESRD patient population as discussed within Section C of this application." However, that is not what FMS's methodology in Section C indicates.

On page 22, FMS defines the project's first two operating years as "Operating Year 1: January 1 through December 31, 2022; Operating Year 2: January 1 through December 31, 2023." Any projected patient dialyzing or receiving support services on December 31, 2021, would be accounted for by the facility in which they were receiving services. However, FMS assumes "50% of new home patients, or 18.30 patients will transfer their care to Wilson Home Dialysis effective December 31, 2021." If FMS is not projecting patients to change dialysis providers, where are

these patients coming from? They certainly are not existing Wilson Home Dialysis patients, since that facility isn't projected to be operational until January 1, 2022.

Given that the proposed project could not possibly begin with 23.30 patients at Wilson Home Dialysis, the facility would have to begin with "the 5 patients served by Fresenius related facilities as of December 31, 2019." This would make FMS's current projections for the ending census for OY1 and OY2 unrealistic.

FMS further compounds the overstatement of its patient projections by claiming on page 24 that it is reasonable to determine new home patients in OY1 by subtracting the existing patients on December 31, 2018 from the projected patients on December 31, 2022. Any projected patient dialyzing or receiving support services through December 31, 2021, would be accounted for by the facility in which they were receiving services. The only "new patients" for the proposed Wilson Home Dialysis project are those in the period of growth between December 31, 2021 and December 31, 2022.

Also, as indicated in Table 9A of the 2020 SMFP, DaVita is serving 37 of the 43 Wilson County PD patients as of December 31, 2018.

| Patient County of Residence | Facility Name | Facility County | Home Hemodialysis Patients | Home Peritoneal Patients | In-Center Patients | Total Patients |
|---|---|---|---|---|---|---|
| Wilson | Wilson Dialysis | Wilson | 0 | 37 | 116 | 153 |
| Wilson | Forest Hills Dialysis | Wilson | 0 | 0 | 103 | 103 |
| Wilson | Sharpsburg Dialysis | Wilson | 0 | 0 | 4 | 4 |
| Wilson | BMA East Rocky Mount | Edgecombe | 0 | 0 | 2 | 2 |
| Wilson | Dialysis Care of Edgecombe County | Edgecombe | 0 | 0 | 2 | 2 |
| Wilson | FMC of Spring Hope | Nash | 0 | 0 | 2 | 2 |
| Wilson | Fresenius Medical Care South Rocky Mount | Nash | 0 | 1 | 2 | 3 |
| Wilson | Greenville Dialysis Center | Pitt | 1 | 1 | 2 | 4 |
| Wilson | Zebulon Kidney Center | Wake | 0 | 0 | 2 | 2 |
| Wilson | Carolina Dialysis Carrboro | Orange | 0 | 0 | 1 | 1 |
| Wilson | FMC Dialysis Services East Carolina | Pitt | 0 | 1 | 1 | 2 |
| Wilson | FMC Farmville | Pitt | 0 | 0 | 1 | 1 |
| Wilson | FMC New Hope Dialysis | Wake | 0 | 0 | 1 | 1 |
| Wilson | Johnston Dialysis Center | Johnston | 0 | 0 | 1 | 1 |
| Wilson | Rocky Mount Kidney Center | Nash | 0 | 0 | 1 | 1 |
| Wilson | Edgecombe Home Dialysis | Edgecombe | 0 | 3 | 0 | 3 |

FMS fails to deduct these 37 existing patients from its projections, which further inflates FMS's projected home patient utilization in OY1 and OY2.

FMS's projected utilization is clearly not based on reasonable assumptions. If the utilization is not based on reasonable assumptions, the project's financials must also be found to be unreliable, and FMS's application is not the most effective alternative.

As a result of the foregoing, FMS's application fails to conform with at least Criteria 3, 4, 5, and 18a.

## II. FMS's Application Fails to Conform With Applicable Review Criteria for Additional Reasons.

The manner in which FMS proposes to offer services is unlawful. An application that proposes to offer health care services in an unlawful manner is necessarily non-conforming to numerous statutory review criteria, including Criteria 3, 4, 5, and 18a.

FMS is a joint venture between BMA and ENA. As stated on page 5, ENA is described as "a physician owned practice with its primary location in Greenville, NC." ENA serves patients requiring dialysis treatment, and on page 18 FMS states that ENA currently serves "a significant number of patients residing in Wilson County" and "patients who reside in Wilson County and have some advanced stage of chronic kidney disease." The application goes on to describe that ENA "also admits patients to the Fresenius related facilities across eastern North Carolina."

Thus, ENA treats the types of patients that are proposed to be served by FMS. ENA will therefore be a referral source to FMS, an entity within which ENA has an ownership interest. ENA makes clear its intent to refer to FMS within the letters of support provided in Exhibit H of the application, where ENA physicians state: "**I will refer patients to Wilson Home Dialysis**."

Self-referral of patients in the manner ENA and FMS propose is unlawful in North Carolina pursuant to N.C. Gen. Stat. § 90-406(a), which **prohibits physicians from making a referral of any patient** to any entity in which the health care provider, his/her group practice, or any other member of the group practice has an **ownership or investment interest**. N.C. Gen. Stat. § 90-406(b) and (c) also prohibit any entity that receives a prohibited referral **from billing for or collecting any amounts** related to services provided pursuant to that referral.

While there are some very limited exceptions to North Carolina's self-referral prohibition, none apply to the FMS project. The definition of "referral" at N.C. Gen. Stat. § 90-405(11) excludes health care services that are provided by, or are provided under the personal supervision of, the physician investor in question. With the FMS project, however, ENA physicians will not be physically present when patients self-administer home hemodialysis or peritoneal dialysis treatments, even though FMS will bill and collect for such services. Therefore, the self-referral prohibition applies to FMS.

An unlawful project is not needed by any proposed patient population. In addition, utilization projections based on and reliant upon an unlawful proposal cannot be reasonable or adequately supported. FMS relies on referrals from ENA for its utilization projections, and therefore FMS's utilization projections are unreliable and FMS has not demonstrated that its project is needed as required by Criterion 3.

Under Criterion 4, FMS is required to demonstrate it has proposed the least costly or most effective alternative for meeting the need for the proposed project. An unlawful proposal will never be the least costly or most effective alternative over a lawful proposal.

Under Criterion 5, FMS is required to demonstrate the immediate and long-term financial feasibility of the proposal, as well as demonstrate this its proposal is based upon reasonable projections of costs and charges. As discussed above, FMS is prohibited from billing or collecting any amounts for services provided due to referrals from ENA. Therefore, FMS's financial projections, which assume collecting revenues related to ENA referrals, are unreasonable and unsupported, and FMS has not demonstrated the immediate or long-term financial feasibility of its project.

Under Criterion 18a, FMS has failed to explain the expected effect on competition that will result from proposing to develop an unlawful project, and FMS cannot show that an unlawful project will have a favorable impact on cost effectiveness, quality, and access to services proposed.

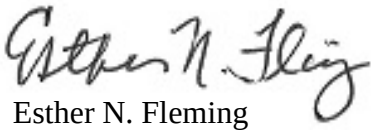
As a result of the foregoing, FMS's application fails to conform with at least Criteria 3, 4, 5, and 18a.

## III. Conclusion

As a result of the foregoing, FMS's application fails to conform with multiple CON review criteria. Upon further review, TRC may determine that additional non-conformities, inconsistencies or errors exist in the FMS application.

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

Sincerely,



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