



October 31, 2022

Via Email (DHSR.CON.Comments@dhhs.nc.gov and donna.donihi@dhhs.nc.gov)

Ms. Donna Donihi, Review 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 FMS
ENA Home, LLC's CON Application**

Project ID#: L-012269-22
Facility: Wilson Home Dialysis
Project Description: Develop one dialysis station to be used exclusively for home hemodialysis training and support services, which is a Change of Scope for CON Project ID# L-11836-20
County: Wilson
FID#: 200032

Dear Ms. Donihi:

Total Renal Care of North Carolina, LLC (**TRC** or **DaVita**) submits the following written comments on the September 15, 2022 CON Application of FMS ENA Home, LLC (**ENA**) to develop one (1) dialysis station to be used exclusively for home hemodialysis training and support services (Project ID # L-012269-22), which is a Change of Scope for CON Project ID # L-11836-20. (Application, p. 15). TRC submits these comments in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to discuss 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. N.C. Gen. Stat. § 131E-185(a1)(1)(b), (c).

Background

ENA is a joint venture between Bio-Medical Applications of North Carolina Inc. (**BMA**), as majority owner, and Eastern Nephrology Associates, PA, as minority owner, and is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. (Application, p. 12). In 2020, ENA submitted a Certificate of Need (**CON**) application to the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (**Agency**) to develop a new dialysis facility, Wilson Home Dialysis, that would be dedicated solely to providing home peritoneal dialysis training and support services, Project ID # L-11836-20. ENA's 2020 Wilson Home Dialysis application did not propose to include any certified in-center stations or home hemodialysis stations as part of its project. (Required State Agency Findings, June 12, 2020, Wilson Home Dialysis, Project ID # L-11836-20, p 1.)

On June 12, 2020, the Agency issued its decision and corresponding Required State Agency Findings in which it determined ENA's Wilson Home Dialysis application was conforming to all applicable statutory review criteria. The Agency determined that the Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C.2200 did not apply to the review as a result of a declaratory ruling issued to BMA on October 10, 2018, "*which exempts the Criteria and Standards from applying to proposals to develop or expand facilities exclusively serving [home hemodialysis] and [peritoneal dialysis] patients.*" (Required State Agency Findings, June 12, 2020, Wilson Home Dialysis, Project ID # L-11836-20, p 24.) On November 13, 2020, the Agency issued a CON to ENA to develop Wilson Home Dialysis on the condition that the facility would "*provide only peritoneal dialysis training and support services.*" (Certificate of Need for Project ID # L-11836-20, pp. 1-2).

Development Rather than Relocation of Dialysis Stations Raises Concerns Regarding Dialysis Station Need and Planning Inventory

At present, Wilson Home Dialysis may only offer home peritoneal dialysis training and support services consistent with Project ID # L-11836-20 and does not have a dialysis station for the training and support of home hemodialysis patients. (2022 SMFP, Table 9E, p. 143). With its current application, ENA now seeks to change the scope of its previously approved Wilson Dialysis Home project (Project ID # L-11836-20) to develop one (1) new dialysis station to be used exclusively for home hemodialysis training and support services. (Application, p. 15). As discussed below, ENA's proposal appears to be inconsistent with the spirit and the letter of the CON law and the 2022 SMFP, and raises concerns regarding dialysis station need and planning inventory that the Agency should consider during this review.

Historically, an applicant seeking to add a hemodialysis station to a dialysis facility dedicated to peritoneal dialysis training and support has sought to relocate an existing hemodialysis station from an in-center facility to the home training facility. The dialysis station that was relocated to the home training facility would then be removed from the SMFP dialysis station county and facility need determination planning inventories (hereinafter, **Need Planning Inventory**). Once relocated dialysis stations are removed from the Need Planning Inventory, they are excluded from

both the county and facility need determination calculations, and tracked on SMFP Table 9E: “Inventory of Dialysis Home Training Facilities”. (2022 SMFP, Table 9E, p. 143).

Instead of seeking to relocate one of BMA’s existing dialysis stations to the Wilson Home Dialysis facility (which would remove an existing dialysis station from the Need Planning Inventory and exclude it from the county and facility need determination calculations), ENA seeks to develop a new dialysis station that does not currently exist in the Need Planning Inventory and for which there is no need determination calculation methodology. Accordingly, ENA’s proposal will increase the overall inventory of dialysis stations in Wilson County, which already has a surplus of 16 dialysis stations, without having to satisfy a county or facility need determination calculation. (2022 SMFP, Tables 9B and 9C, pp. 138-139). This seems contrary to the CON law, which requires an applicant to first demonstrate that its proposal is consistent with all applicable review criteria, including any need determinations in the SMFP, and performance standards before obtaining a CON. N.C. Gen. Stat. §§ 131E-183(a), -183(b).

Although ENA acknowledges that “*there is no need methodology in the 2022 SMFP to add a station at an existing freestanding home therapies facility,*” it contends that the development of a new station at a freestanding home therapies facility is proper because it is supported by the following Assumptions of the Methodology in Chapter 9 of the 2022 SMFP:

- “Home patients will not be included in the determination of need for new stations. Home patients include those that receive hemodialysis or peritoneal dialysis in their home.”
- “Once a CON application has been received to relocate stations to a home training facility, the stations to be relocated are excluded from both the county and facility need determination calculations.”

(Application, p. 16; 2022 SMFP, Chapter 9, Assumptions of the Methodology (Nos. 1 and 7), p. 116) (emphasis added). Relying on these assumptions, ENA reasons that “*if the relocation of stations to a home training facility are excluded from both the county and facility need determination calculations because home dialysis patients will not be included in the determination of need for new stations, the development of stations at a freestanding home training facility should also be excluded from both the county and facility need determination calculations.*” (Application, p. 16) (emphasis added). However, the plain language of the 2022 SMFP does not appear to support ENA’s rationale.

There is a difference between relocating an existing hemodialysis station to a dialysis facility to be used for home hemodialysis and peritoneal dialysis training and support services and the development of a new hemodialysis station to be used at that facility, especially since the former removes an existing dialysis station from the Need Planning Inventory. This difference is evident from the new additions to Chapter 9 of the 2022 SMFP.

Chapter 9 of the SMFP was revised to include a definition for “home training facility”, which is a “*facility dedicated exclusively to train hemodialysis or peritoneal dialysis patients to dialyze at home or at a location other than a kidney disease treatment center, as defined in G.S. 131E-176(14e).*” Second, Chapter 9 of the SMFP was revised to add Assumption No. 7 to the ESRD

“Assumptions of the Methodology”. (2022 SMFP, p.116 ; 2021 SMFP, p. 114). Assumption No. 7 provides “[o]nce a *CON* application has been received to relocate stations to a home training facility, the stations to be relocated are excluded from both the county and facility need determination calculations.” (emphasis added). The simultaneous additions of the definition of “home training facility” and Assumption No. 7, considered together, indicate that the State Health Coordinating Council (SHCC) does not equate relocation of existing dialysis stations with the development of new dialysis stations, and does not intend for the development of a new dialysis station at a home training facility to be excluded from the county and facility need determination calculations. Rather, such additions suggest that the SHCC intended that only where there is a relocation of existing dialysis stations to a home training facility (rather than the development of new stations) are the stations excluded from both the county and facility need determination calculations.

Had the SHCC wanted to exclude newly developed dialysis stations dedicated for use at a home training facility from both the county and facility need determination calculations, it could have included that language in Assumption No. 7 or another Assumption of the Methodology in the 2022 SMFP. This is especially true since on January 1, 2021, only one year prior to implementation of the 2022 SMFP, the Performance Standards for ESRD Services, codified at 10A NCAC 14C.2203, were amended to include standards for documenting need for both the (1) establishment of a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training and (2) addition of home hemodialysis stations to such facilities. 10A NCAC 14C.2203(c); 10A NCAC 14C.2203(d). Yet despite this amendment, which occurred during the planning of the 2022 SMFP, the SHCC chose not to include in Chapter 9 of the 2022 SMFP an assumption that newly developed dialysis stations dedicated for use at a home training facility would be excluded from both the county and facility need determination calculations, which further signals that the SHCC did not intend for newly developed dialysis stations dedicated for use at a home training facility to be excluded from the county and facility need determination calculations.

If this type of proposal is permitted, it arguably paves a path for future applicants to develop an in-center dialysis facility in a county in which it otherwise would not have one by circumventing county and/or facility need determinations. Stated differently, the development of a new dialysis station at an ESRD facility that has been approved for home training only ultimately could be used by future applicants as a springboard to develop a new 10-station in-center ESRD facility in a county where there is no county or facility need determination.

As the Agency is aware, a new ESRD facility requires at least ten (10) dialysis stations, one of which can be designated solely for use of home hemodialysis training and services (2022 SMFP, Chapter 9, p. 116). Ordinarily, an applicant seeking to develop a new 10-station ESRD facility must satisfy the requisite county or facility need determination. But where an applicant is unable to apply for a new 10-station dialysis facility due to a lack of facility and county need, it could apply to develop a dialysis facility that would offer home training and services to peritoneal dialysis patients only. That same applicant could then later apply to add a hemodialysis station to that same facility, which if approved, would allow that facility to be certified for both home hemodialysis and peritoneal dialysis training and support services. Indeed, there is nothing

preventing that same applicant from further applying in the future for additional changes of scope to its previous application to ultimately develop a 10-station in-center dialysis facility without having to satisfy the county or facility need determinations, including through: (a) developing at least nine (9) additional dialysis stations dedicated to home hemodialysis training and thereafter requesting to convert those nine (9) stations to in-center stations; (b) relocating nine (9) existing dialysis stations from another facility to the home training facility pursuant to Policy ESRD-2; and/or (c) increasing the number of home hemodialysis stations at the home facility either through development or relocation of dialysis stations. This could be particularly problematic where there is no demonstrated need for dialysis stations in the county at issue.

At its most basic level, this type of proposal would permit an applicant to develop a dialysis station that is not contained in the Need Planning Inventory. This result seems inconsistent with the CON law and “Assumptions of the Methodology” in Chapter 9 of the 2022 SMFP. However, such a proposal would appear to be consistent with the CON law and “Assumptions of the Methodology” in Chapter 9 of the 2022 SMFP if all of the following are true:

- Any dialysis station that is developed at a home training facility for the dedicated use of home hemodialysis training and support services is included in the SMFP Inventory of Dialysis Home Training Facilities and is never allowed to be included in the Need Planning Inventory or the county and facility need determination calculations since the station dedicated to home hemodialysis training and support services is created outside of the Need Planning Inventory;
- Any existing dialysis station that is relocated to a home training facility for the dedicated use of home hemodialysis training and support services is included in the SMFP Inventory of Dialysis Home Training Facilities and is never allowed to be added back into the Need Planning Inventory or the county and facility need determination calculations since the station dedicated to home hemodialysis training and support services is removed from the Need Planning Inventory; and
- Any addition of or increase in dialysis stations at a home training facility for the dedicated use of home hemodialysis training and support services is included in the SMFP Inventory of Dialysis Home Training Facilities and is never allowed to be included in the Need Planning Inventory or the county and facility need determination calculations since those stations would either be developed or relocated, *i.e.*, created outside of or removed from the Need Planning Inventory.

Regardless of how dialysis stations to be used exclusively for home hemodialysis training and support services come into existence at a home training facility (*i.e.*, development, relocation, or other increase), it would make sense for those stations to be included in the Inventory of Dialysis Home Training Facilities and to never allow those stations to enter into (in the case of development) or to come back into (in the case of relocation) the Need Planning Inventory or to be included in the county and facility need determination calculations. This would appear to be consistent with the CON law and Chapter 9 Assumptions of the Methodology in the 2022 SMFP

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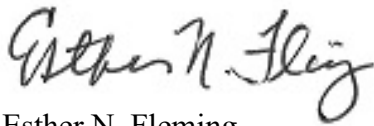
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and would prevent an applicant from using home hemodialysis stations to develop an in-center dialysis facility without having to satisfy a county or facility need determination.

If the Agency ultimately concludes that this type of proposal is permissible, the Agency should consider conditioning the approval of an applicant's proposal to develop a hemodialysis station at a home training facility on that station (a) being included in the SMFP Inventory of Dialysis Home Training Facilities and (b) never coming into the Need Planning Inventory since such a condition would seem to be consistent with how the SHCC and the Agency treat relocated dialysis stations as well as the spirit and letter of the CON law and Chapter 9 of the 2022 SMFP.

Thank you very much for your review and consideration of these issues during the review.

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