

**Piedmont Dialysis Center of Wake Forest’s Comments regarding the Edgecombe Home Dialysis CON proposed by BMA – an existing home dialysis training facility with 2 PD training stations and a proposal to add 1 “dedicated” HH training station, currently following 35 PD patients and no HH patients:**

- CMS Survey and Certification requires a facility requesting certification to provide home hemodialysis training and support to have one new home hemodialysis patient to train during the survey and certification process. Applicant projects 4 existing home hemodialysis patients will transfer their follow-up care to Edgecombe Home Dialysis, and those patients will grow to 4.7 home hemodialysis patients by the end of OY2 of the proposed project. However, by the project’s certification date 12/31/2020, the applicant does not project a single **new** home hemodialysis patient, which it is required to have to obtain CMS certification for the service.
- The applicant doesn’t project via Form C., Utilization, or in the methodology and assumptions contained in Section C and Section Q of its application that it will provide a single home dialysis training treatment for either HH or PD. In fact, the applicant projects its number of PD patients will decline to 34.5 by the end of OY2.
- The applicant indicates in the last paragraph on page 22 of its application that the population to be served by the proposed project (seeking to transfer an ICH station to a home dialysis training facility for the purposes of home hemodialysis training and support) consists of the 4 existing home hemodialysis patients who will transfer their support care to the facility.
- Section C., 6., page 25 of the Applicant’s CON application requires the applicant to provide historical and projected annual **utilization** data. **Dialysis training stations are only utilized by patients receiving training or re-training for their chosen modality.** No such patients are included on Form C, described in the methodology, or assumptions included in Section C.
- Applicant fails to describe the “need” patients already dialyzing at home have for **PD training** stations and **HH training** stations nor what service a **training** station provides to an existing home dialysis patient already performing their dialysis at home. In fact the applicant states at the top of page 19 what is involved when an existing home patient visits the clinic for monthly follow up. Utilization of a dialysis **training** station is not described.
- Applicant fails to indicate revenue for the **performance of home dialysis training** for any modality during any operating period, even though the station it requests is for the delivery of home dialysis **training** only – not hemodialysis performed at home nor peritoneal dialysis performed at home.
- Applicant fails to indicate revenue for the performance of home dialysis re-training for any modality during any operating period.
- “Support” of a home dialysis patient does not require a single home dialysis **training** station. Applicant fails to show the need that home dialysis patients performing their dialysis at home have for the proposed home **training services** and/or home **training stations**.

The following are important to note regarding home dialysis training and the space requirements to develop a robust home training program:

- Home hemodialysis training patients train at the ESRD Treatment Facility about 25 days, then take home the machine on which they train to perform their dialysis treatments at home.
- Home peritoneal training patients train about 7 – 10 days, then take home the machine they train on to perform their dialysis treatments at home.
- Support of the home dialysis patient includes monthly visits to the dialysis clinic for lab draws and other non-training related services.
- While home hemodialysis training is going on the patient is actually receiving a hemodialysis treatment in the home training facility. This is the primary reason ICH facilities without “dedicated” home hemodialysis training stations must “down” a station in their treatment bays while home hemodialysis training is ongoing – to ensure they are not performing ICH on more stations than for which they are certified.

It is our position that the application submitted by BMA fails to demonstrate the need the proposed patient population—**consisting of patients already dialyzing at home**—has for the proposed service (***the addition of a home hemodialysis training station***) because the applicant fails to show it will have even one **new** patient to **train** for **home hemodialysis** as of the proposed certification date of the project, as is required by the CMS Survey and Certification Section. Additionally, the applicant fails to show it will provide home dialysis **training** to even one patient in the future nor that it has provided such services to even one patient past or present. Further, we believe because of this failure to demonstrate need via the number of patients the applicant projects to train, particularly, one new home hemodialysis patient as of the certification of the proposed project, the Edgecombe Home Dialysis Application fails to conform to Criterion 3, and thereby, fails to conform to Criterion 1.

The applicant fails to demonstrate the need the proposed patient population (consisting of patients already dialyzing at home) has for even one home hemodialysis **training** station. Without demonstrating the need the projected patient population has for the proposed service, the proposed service unnecessarily duplicates existing and approved services in the service area and approval of this CON would ultimately undermine the basic principles of the entire CON program. Thus, it should be denied.