

Piedmont Dialysis Center of Wake Forest’s Comments regarding the INS Freedom Lake CON proposed by BMA – a 16-station home dialysis training facility with 11 PD training stations and 5 HH training stations following 8 HH patients and 20 PD patients already dialyzing at home that are projected to grow to 12 HH patients and 28 PD patients dialyzing at home by the end of OY2 of the proposed project representing an increase of 1 HH patient per OY and an increase of 2 PD patients per OY:

- Applicant states one HH training station can train up to 8 patients per year on page 24, paragraph 3 of its application. Applicant can train up to 16 HH patients per year on its existing two HH training stations. Applicant projects to increase its existing HH patients by 1 HH patient per year, yet fails to explain how that increase cannot be achieved on its existing two HH training stations.
- Applicant fails to state the number of PD training patients who can train per PD training station per year. Applicant projects to increase its PD patients by 2 PD patients per year, yet fails to explain how that cannot be achieved on more than one PD training station, while proposing a facility with 11 PD training stations.
- 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.
- Applicant fails to describe the number of patients it trained during the last OY – **those who utilized the facility’s home dialysis training stations** – as required in Section C.
- Applicant fails to describe the number of patients (based upon its more than 10-years’ experience operating as a Home Dialysis Training Facility) it can reasonably project to train on its requested **11 PD training** stations and **5 HH training** stations.
- Applicant fails to indicate the number of patients who are dialyzing at home that have or may require re-training at any time past or present. Nor does the applicant project how many existing patients may require re-training in the future or the impact retraining will have on its ability to meet the demands to **train** new patients for PD or HH.
- Applicant fails to indicate revenue for the **performance of home dialysis training** for any modality during any operating period, even though the stations it requests are for the delivery of home dialysis **training** only – not in-center PD nor ICH.
- 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***.
- After 10 years or more operating as a home dialysis training facility, the applicant provided no data as to far as:
 - number of patients home trained per year
 - net number of patients successful in their training (completed all training days and continued to dialyze at home one-year after training)
 - failure rates (total patients trained versus those continuing to dialyze at home after one year)
 - gross total patients home-trained by modality by year
 - growth rates in training numbers year over year
 - average home training days per patient by modality
 - justification that the existing number of PD and HH training stations is inadequate to meet the demand for the service
 - projections of revenue for providing home training – the service for which the **9,000+ square foot** facility is intended

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** plus one new HH patient and 2 new PD patients per year—has for the proposed service (**11 PD home dialysis training stations** and **5 HH home dialysis training stations**) because it 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, the INS Freedom Lake 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 home dialysis ***training*** stations. 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.