

Piedmont Dialysis Center of Wake Forest's Comments regarding the FMC Sea Spray CON proposed by BMA – a 10-station ICH facility providing ICH, PD home dialysis training, and HH home dialysis training on ICH stations, which requests to transfer 2 ICH stations from Crystal Coast Dialysis to be used exclusively for the provision of home hemodialysis training and support. Currently, the facility downs an ICH station during home hemodialysis training.

- Applicant states the need to dedicate two stations to home hemodialysis training in order to free up ICH stations to perform ICH treatments on transient patients. However, the applicant fails to state any number of new patients it projects to **train** during any OY for home hemodialysis.
- Applicant indicates its home hemodialysis patient population will increase by about 1.9 total patients over the next 4 years or about 0.5 new HH patients per year. However, the projected increase in the home hemodialysis patient population reported by the facility as described on page 22 of the applicant's CON application does not state the total number of patients the applicant proposes to train on its two "**dedicated**" home hemodialysis **training** stations only that the need to perform dedicated ICH treatments on its certified ICH stations requires it to need "**dedicated**" home hemodialysis **training** stations.
- Applicant has stated in other similar applications (INS-Freedom Lake) that one home hemodialysis training station can train up to 8 home hemodialysis patients per year. Applicant fails to describe how the 0.5 projected new HH patients per year will require more than one "**dedicated**" HH training station for their home hemodialysis **training**.
- 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 it can reasonably project to train on its requested **2 "Dedicated" 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 of HH.

- Applicant fails to indicate revenue for the **performance of home dialysis training** for any modality during any operating period, even though the requested transfer of two ICH stations are for the “**dedicated**” delivery of home hemodialysis **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**.
- While the applicant is certified to provide ICH services and projects enough ICH patients to justify the addition of two new ICH stations according to the ESRD Performance Standards, the applicant proposes that the two stations it will add will be “**dedicated**” to **home hemodialysis training** – not for use as ICH stations. Therefore, the fact that the applicant projects enough ICH patients to meet the performance standards for all 12 stations is irrelevant to demonstrating the need for **two “dedicated” home hemodialysis training stations**.
- Although the applicant has provided home hemodialysis training in the past by downing an ICH station in its bay treatment area, the applicant provided no data as to:
 - 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 HH training stations (1 flex ICH stations) is inadequate to meet the demand for the service

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.

- Yet, the need to perform ICH on all certified ICH stations as indicated in the FMC Sea Spray application does not justify a “need” for dedicated home hemodialysis training stations in an ICH facility without a projection to train at least one patient to perform home hemodialysis during even one OY.

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 0.5 new HH patients per year—has for the proposed service (**2 “Dedicated” HH training stations**) because the applicant fails to show it will provide home dialysis **training** services to even one patient past or present via Form C or Form F.2. Further, we believe because of this failure to demonstrate need via the number of patients the applicant projects to train, the FMC Sea Spray 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 **2 “Dedicated” home hemodialysis 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.