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August 25, 2020

Ms. Nadine Pfeiffer, Rules Review Manager
Ms. Martha Frisone, Chief Healthcare Planning and Certificate of Need
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Proposed changes to Rules

Dear Ms. Pfeiffer and Ms. Frisone:

The following comments on proposed rule changes are offered on behalf of Fresenius Medical Care and its related dialysis facilities in North Carolina:

A. 10A NCAC 14C .2201 Definitions

The proposed definition for #3, "Dialysis station" would seem to include peritoneal dialysis training areas. The proposed rule indicates that a dialysis station would include the treatment area used to accommodate the equipment and supplies needed to perform dialysis on a single patient.

Peritoneal dialysis patients do receive dialysis treatment as a part of their training regimen. Therefore the rule as written seems to include the peritoneal dialysis training areas where equipment and supplies needed for dialysis are maintained during the treatment.

This is a departure from the long held practice wherein peritoneal dialysis training was not considered to be a dialysis station.

Is it the intent of this new definition to include peritoneal dialysis training as a dialysis station?

We do not think this was the intent of the definition. However, in order to clarify this ambiguity, it would be best to write the definition as:

Dialysis station means the treatment area used to accommodate the equipment and supplies needed to perform hemodialysis on a single patient.

The proposed definition for # 5 “Home hemodialysis” indicates that the hemodialysis treatment is performed “in the patient’s home”. This definition seems to be restrictive and does not truly comport with the reality of home dialysis today.

Certainly many patients may perform all of their home hemodialysis treatment within their residence. However, many others travel with their home hemodialysis equipment and supplies. Home hemodialysis may be performed at the patient’s office or place of employment. Home hemodialysis may be performed at a vacation location, or secondary residence. It is somewhat misleading to suggest that home hemodialysis can only be performed “in the patient’s home”.

Rather, an alternative definition for home hemodialysis might be written as:

Home hemodialysis means hemodialysis performed by a patient (trained in hemodialysis) at a location other than the in-center dialysis treatment facility.

The proposed definition for # 7 “Peritoneal dialysis”, similar to home hemodialysis, indicates that the dialysis treatment is performed “in the patient’s home”. This definition seems to be restrictive and does not truly comport with the reality of home dialysis today.

For the same reasons as noted above, we suggest a more appropriate wording for the definition might be:

Peritoneal dialysis means the form of dialysis performed by a patient (trained in peritoneal dialysis) at a location other than the in-center dialysis treatment facility.

B. 10A NCAC 14C .2203 PERFORMAN STANDARDS

First, we recognize that the performance standard currently is based upon station utilization of 2.8 in-center patients per station. We would respectfully suggest that the performance standard should be increased to 3.5 patients per station. It seems the lower utilization allows for excessive stations to be developed.

Secondly, the proposed 2203 (c) performance standard requires 6 home hemodialysis patients per station per year as of the end of the first full fiscal year of operation. There is currently movement within the dialysis population for more patients to do home dialysis. Certainly more patients are choosing home dialysis and within those numbers a high percentage are choosing home hemodialysis. The President’s Executive Order from July 2019 recognizes that more patients should be dialyzing on home dialysis. We suggest that it is premature to impose a performance standard of six patients per station. Rather, this standard might be best imposed after another year or two. Let’s first roll out more home programs and get more patients on home dialysis before requiring any specific number of patients per station.

If you have any questions, please feel free to contact me at 910-568-3041, or via email jim.swann@fmc-na.com.

Very truly yours,

A handwritten signature in blue ink, appearing to read "Jim Swann". The signature is stylized and fluid, with a long horizontal stroke extending to the right.

Jim Swann, Director, Certificate of Need