



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

REPORT OF PUBLIC HEARING

August 25, 2020

10:00 A.M.

Via WebEx

Division Staff Present:

Nadine Pfeiffer, Rule-review Manager

Diana Barbry, Rule-making Assistant

Martha Frisone, Healthcare Planning and Certificate of Need

Amy Craddock, Healthcare Planning and Certificate of Need

Lisa Pittman, Healthcare Planning and Certificate of Need

Others Present:

Dana Gillikin, Division of Marine Fisheries

Esther Fleming, Davita

Jim Swann, Fresenius Medical Care

Matt Fisher, Poyner & Spruill

Hannah Jernigan, Private citizen

Kimberly Clark, Health Systems Management & The Wake Forest Dialysis Centers

William McDonald, Health Systems of Wake Forest Dialysis

Elizabeth Runyon, UNC Health

Purpose of Hearing

This is the public hearing for the proposed rule readoption and fiscal note for 10 Certificate of Need rules. These rules are 10A NCAC 14C .0202, .0203, .0205, .0303, .2101, .2103, .2201, .2203, .3901, and .3903. The purpose of this meeting is not to discuss or debate these rules but rather, to accept comments from the public on these proposed rules and fiscal note that was prepared for these rules.

Hearing Summary

The public hearing was opened via WebEx by Nadine Pfeiffer at 10:03 a.m. Attending via WebEx and conference call were eight members of the public as listed above. One oral comment was recorded for the rules as follows:

Jim Swann, Fresenius Medical Care stated that under the proposed definition for number three, “dialysis station,” it seems to include peritoneal dialysis training areas. The proposed rule indicates that the dialysis station will include the treatment area used to accommodate the

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

OFFICE OF THE DIRECTOR

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 2701 Mail Service Center, Raleigh, NC 27699-2701
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3750 • FAX: 919-733-2757

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equipment and supplies needed to perform dialysis on a single patient. Mr. Swann stated that peritoneal dialysis patients do receive a dialysis treatment as a part of their training regimen. Therefore, he suggested the rule as it is written seems to include that peritoneal dialysis training areas where equipment and supplies needed for dialysis, are maintained during the treatment. Mr. Swann stated that he sees this as a departure from the long-held practice where peritoneal dialysis training was not considered to be a dialysis station. Mr. Swann questioned whether the attempt of this definition is to include peritoneal dialysis as a dialysis station. He stated, "I don't think it is," but in order to clarify this ambiguity he suggested that the definition be rewritten as, "dialysis station means the treatment area used to accommodate the equipment and supplies needed to perform hemodialysis on a single patient."

Mr. Swann stated the proposed definition for number five, "home hemodialysis," indicates that home hemodialysis is performed in the patient's home. He stated this definition seems to be a bit restrictive and does not really comport with the reality of home dialysis today. Mr. Swann said that while certainly many patients perform all of their home hemodialysis treatments within their residence, there are many others that perform that same hemodialysis treatment in their office or their place of an employment. Home hemodialysis may be performed with a medication location or a secondary residence. He stated, "I think it is somewhat deceiving to suggest that home hemodialysis is only done in the patient's home." Mr. Swann stated an alternative definition for home hemodialysis might be written as, "home hemodialysis means hemodialysis performed by a patient trained in hemodialysis receiving the treatment at a location other than in-center dialysis treatment facility."

Mr. Swann stated he had similar comments for the peritoneal dialysis but did not think all the peritoneal dialysis receive all of their treatments in their home. He suggested that the definition could be rewritten to say, "peritoneal dialysis means the form of dialysis performed by a patient trained in peritoneal dialysis and receiving a treatment at a location other than the dialysis treatment center."

Mr. Swann stated he was then moving on to the performance standards, and stated he thought we have talked about this in the past. He said that rather than using the 2.8 in-center patients per station, since this is comments about the standard, he thought 2.8 is low and is going to lead to excessive developments or developments of unnecessary stations. Mr. Swann suggested that the performance standards be increased to 3.5 patients per station for control of the dialysis stations inventory.

Mr. Swann stated another part of the (Rule) .2203 performance standard relates to the requirements for home hemodialysis stations. He said starting next year, the agency seems to be wanting to see six home hemodialysis patients per station. Mr. Swann suggested that with the President's Executive Order from last year and the swing in the direction of more patients doing home dialysis and especially more patients doing home hemodialysis, right now might not be the best time to implement a required standard of any performance, but continue in the same mode that we currently have where there is no performance standard for home hemodialysis. He stated, "Let's get this home hemodialysis more readily available across the state." There are some facilities that are only going to have maybe four patients per year as opposed to six patients per year. Mr. Swann stated that while a physician will train more patients than six, the patient

has to complete the training to go home for home hemodialysis for that patient to be counted. There are many more patients that begin training but don't complete the training. He said he thought it is premature to suggest that it needs to be six patients per home hemodialysis station per year. Mr. Swann suggested that we continue with no requirements for performance standards for at least another year and possibly two more years as home dialysis ramps up more across the state.

Adjournment

These comments will be taken into consideration by the Agency. The hearing was adjourned at 10:16 a.m.

Respectfully Submitted,



Nadine Pfeiffer, Rule-review Manager
August 27, 2020

Attachment

