



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**
Division of Health Service Regulation

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director

REPORT OF PUBLIC HEARING
DECEMBER 5, 2019
10:00 A.M.

Division Staff Present:

Nadine Pfeiffer, DHSR Rule-review Manager
Diana Barbry, DHSR Rule Assistant
Martha Frisone, Chief, Certificate of Need
Lisa Pittman, Assistant Chief, Certificate of Need
Gloria Hale, Certificate of Need

Others Present:

Esther Fleming, DaVita
Jim Swann, Fresenius Medical Care

1. Purpose of Hearing

The purpose of this public hearing was to solicit verbal and/or written comments for the proposed temporary rule amendments for the Certificate of Need rule 10A NCAC 14C .2203.

2. Hearing Summary

The Public Hearing was opened by Nadine Pfeiffer at 10:03 a.m. Attending was a representative from DaVita; however they did not wish to offer comments. The meeting was recessed at 10:04 a.m. for 20 minutes to allow for more members of the public to attend. During the recess, a representative from Fresenius Medical Care came to the meeting. The meeting was reconvened at 10:24 a.m., at which time, one oral comment was recorded for the rule. The oral comments recorded are as follows:

Jim Swann, Fresenius Medical Care

The following comments are offered on behalf of all Fresenius Medical Care related dialysis facilities operating in North Carolina.

We strongly oppose this reduction in the required performance standards. In fact, we would recommend an increase to the performance standard from 80% to 85%.

The 80% performance standard has been in use for many years. Providers and the CON Agency have successfully and comfortably relied upon the current 80% utilization

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standard for many years. Lowering the performance standard will lead to surplus and unnecessary duplication of dialysis stations.

- A review of the proposed 2020 SMFP indicates that 60 of the 100 counties in North Carolina already have a surplus of dialysis stations.
- Look back at the January 2014 SDR. This SDR reports that 50 North Carolina counties had a surplus of dialysis stations.
- Compare this to the January 2004 SDR. At that point the SDR reported only 38 North Carolina Counties with a surplus of stations.
- As you consider these numbers, keep in mind that only 87 of the 100 counties in North Carolina have existing or approved dialysis stations. Thus, 68.97% of our counties have a surplus of stations.
- And this surplus is further compounded when you consider that the Proposed 2020 SMFP indicates 110 dialysis facilities across the state could apply for up to 885 new dialysis stations. Most of these are in counties with surplus inventories already.

On July 10th of this year, President Trump Issued an Executive Order on Advancing American Kidney Health. One part of this Order very clearly favors increasing home dialysis care, and less reliance upon the more traditional model of in-center care.

FMC has already experienced growth in the home patient population; we are seeing more patients admitted to home dialysis, and fewer patients referred for in-center dialysis. The CON Agency will see the first reports confirming this shift in February 2020 as the 2019 year end ESRD Data Collection Forms are submitted.

Obviously I can't speak for other providers, except to say they must deal with the same Executive Order and the must realize the same emphasis by CMS for more patients to dialyze at home.

In our State Health Planning process, home patients are expressly excluded from station need determinations. With more patients doing home dialysis, there is going to be less need for new dialysis stations. Couple this paradigm shift – more patients dialyzing at home – with the station surplus that already exists in 60 counties. There is no compelling reason to reduce the utilization standard from 80% to 70%. Such a reduction will only serve to exacerbate the increasing surplus of dialysis stations.

CON applicants have always had opportunity to prove their station needs. Applicants have only had to demonstrate their methodology was reasonable, and then demonstrate conformity with the performance standards.

In my 15+ years of preparing CON applications for new dialysis stations, less than 1% of our applications have been denied for failure to meet the 80% utilization threshold. That

is less than five applications, over a greater than 15 year period. Less than five in 500 applications have been denied for failure to meet the required 80% utilization standard.

And this has been because the 80% number is achievable.

I applaud the CON Agency for reviewing the standards and considering ways in which to enhance access to care for patients in need. But today, we don't have a serious deficit of stations in any county, except of course those 13 counties where a dialysis facility does not currently exist. It is unfortunate, but a facility does not exist in these 13 counties because of the nature of our planning process – not because of the performance standard.

Respectfully, we strongly oppose the lowering of the performance standard.

3. Adjournment

These comments will be taken into consideration by the Agency. The hearing was adjourned at 10:30 a.m.

Respectfully Submitted,

A handwritten signature in cursive script, reading "Nadine Pfeiffer".

Nadine Pfeiffer, Rule-review Manager
December 5, 2019

Attachment

Public Hearing Attendance
 Certificate of Need Temporary Rules
 10A NCAC 14C .2203
 December 5, 2019 10:00 a.m.

Please print information below:

Name	Representing	Speaking Yes(Y)No(N)
Esther Fleming	Dallita	N
Tim Searns	Fare Fresius Medical Care	Y