FRESENIUS KIDNEY CARE

Certificate of Need
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July 24, 2019

North Carolina State Health Coordinating Council
c/o NC Division of Health Service Regulation
Via Hand Delivery

Re: Public Comments as related to planning for End Stage Renal Disease in the 2020 State Medical Facilities Plan

Dear Members of the SHCC:

Thank you for the opportunity to present comments regarding the Proposed 2020 State Medical Facilities Health Plan. As some of you will know, I have appeared at several of the SHCC public hearings over the most recent weeks.

I am here not just on behalf of Fresenius Medical Care and its related dialysis facilities across the State, but also on behalf of the more than 10,000 dialysis patients we serve within our North Carolina dialysis facilities.

Over the course of the past 15 months we—providers, DHSR Staff, and the SHCC—have worked to find a way forward which would radically change the planning and need methodology for ESRD facilities. When this began, the idea was to eliminate the Semi-Annual Dialysis Report and merge the dialysis planning and need determinations into the State Medical Facilities Plan. In short, we were moving from a twice per year planning and reporting cycle, to a once per year cycle.

The Methodology as currently drafted is not sufficient to ensure adequate access to care for the ESRD patient population across the State of North Carolina. If anything, it will produce unnecessary duplication of services in areas which are already well served, while unfortunately leaving voids in some areas of need.

I'm not saying in any way that Ms. Brown, Dr. Dixon, Dr. Craddock, Ms. Frisone and others from the DHSR Staff have not tried.

I'm not saying that the Acute Care Committee has not tried.

I will say that to the best of my knowledge, none of these folks have been directly involved in delivering dialysis care and treatment to dialysis patients. Rather their role has been as regulators, and policy makers.

Our organization, along with the other providers in North Carolina, provide dialysis care to patients on a daily basis. We know the patients, their ailments, their needs, and we know about their compromised health.

And, just like the DHSR Staff, along with the Acute Care Committee members, we've tried very hard to find the right way forward—a way which allows for elimination of the SDR, and a way which incorporates dialysis into the SMFP, just like other regulated health services.

As a collective group, we—Fresenius, DaVita and Wake Forest Baptist (through their managing agency, Health Systems Management)—we have embraced the annual reporting and yet we have not embraced the methodology as drafted by the DHSR Staff. Collectively, to the best of my knowledge, we've had all of the dialysis facilities in North Carolina represented except for seven facilities (four DCI facilities in Cleveland County, two DSI facilities in Mecklenburg County, and the CMC facility in Mecklenburg County).

So, the SHCC has the overwhelming support of the industry to move to an annual reporting mechanism.

But, the SHCC does not have agreement by the providers with regard to the methodology. The Acute Care Committee and DHSR Staff appear to be promoting a methodology which the providers do not see as a reasonable solution.

After the Public Hearing in Concord, I had a short discussion with Dr. Ullrich regarding the methodology. Dr. Ullrich reminded me that petitions regarding methodology are to be received in the spring, and not the summer. I can't dispute this.

I realize that in general, petitions regarding changes to methodologies should be submitted in the spring. We don't mean to abridge the State Health Plan schedule. But, I can say, and do say to you, the SHCC, throughout the Interested Parties meetings held with dialysis providers, we've been encouraged to appear at the summer Public Hearings and offer comments about the changes to the dialysis chapter in the Plan.

The SHCC has the opportunity to take up this issue, regardless of the schedule. The SHCC can effect appropriate change to the methodology, even at this late date in the process. Don't be trapped by the guidelines.

Working together, with a unified vision for success, we can ensure that the way forward will not impede access to care, while simultaneously not over saturating any service area with un-needed, duplicative dialysis stations.

At yesterday's public hearing in Greenville, I, and Ms. Fleming from DaVita, were able to speak with Ms. Frisone. As you would expect, we spoke about the change to a once per year process, and the draft methodology.

I am submitting a petition for change. We believe that the dialysis patients and providers can be better served by a policy approach, as opposed to the methodology prescribed within the draft plan.

A policy approach is not a new idea. There are other health services, diagnostic centers for example, which don't have a methodology, but are regulated by policy.

A policy could be as simple as allowing any facility operating at or above 80% utilization to apply for additional stations. It would be incumbent upon the applicant to justify the need for more stations, and meet the performance standards as included at 10A NCAC 14C .2203.

A policy approach eliminates the need for a two tiered approach to Facility Need Methodology.

A policy approach is really no different than what we have in place today. While the Methodology does produce a finite number of stations for which a facility can apply, the performance standard serves as the ceiling for the application. More than once in my 15 years of writing CON applications, I've seen the Methodology produce more stations than I could possibly justify when considering the requirements of the performance standard, or more stations than the facility could physically accommodate.

- The Facility Need Methodology

Throughout this series of public hearings, I have advocated for a change to the current methodology. I've expressed that the minimum utilization threshold should be increased to 85%, not lowered to 70%.

I still believe that the utilization threshold should not be reduced, but rather should be increased to 85%. The currently drafted lower utilization rate appears to contribute to an over-abundance of dialysis stations. Table 9b of the Draft plan identifies a total need of 874 new dialysis stations. This would allow for an increase of greater than 15% over the current number of dialysis stations (certified, CON issued and not certified, Conditional Approvals, and Decision Pending). Yet, the ESRD patient population is increasing at a rate of less than 4% annually. Additionally, more patients are choosing home dialysis, meaning fewer dialysis stations will be needed. Recently, even President Trump, surrounded by representatives from across the industry, has suggested that more patients will be doing home dialysis.

If you measure the annual change of the total ESRD patient population in our state, and the total home patient population, in the same manner as the county five year average annual change rate is calculated, you'll see that home patient growth is already 50% higher than the total growth. The overall ESRD patient population is increasing at 3.92% for the five years ended December 31, 2018. In the same five year period, the home patient growth was 5.92%. And in 2018, the last measured year, the home growth was 6.5% as oppose to overall growth of 3.8%. Obviously more patients than ever before are dialyzing at home.

I've just learned this morning more about the CMS proposal that was release on July 10. CMS is proposing to adjust payments to nephrologist and dialysis providers who improve the number of patients treated with home dialysis or who achieve a higher rate of kidney transplantation. The goal of this new plan is to increase the number of patients receiving home dialysis and/or kidney transplantation, and reduce Medicare costs. CMS is proposing that this will be mandatory for 50% of the ESRD facilities and clinicians caring for patients. Such a proposal is going to have significant impact on the number of patients dialyzing in-center and at home. Ultimately, more patients will dialyze at home, and fewer patients will dialyze in-center.

We do not need to saturate the market place with dialysis stations.

- The application planning schedule

Moving briefly to the CON application planning schedule which is included on page 14 of the Draft plan, it seems that the new schedule severely restricts our opportunities to relocate stations across county lines and within a service area. The schedule offers only a once per year opportunity to move stations across county lines pursuant to Policy ESRD-2. We respectfully suggest that moving stations across county lines is no different than an application to move stations within the service area. We therefore recommend that the Category D.2 and D.3 should be combined. Further, the December 1 review for Category D.1 reviews should be changed to allow for station relocation applications.
This change would allow dialysis applications six times per year, in much the same manner as we have been doing. The April and October reviews have worked well for the new station applications. This would allow for relocation application reviews to commence in February, June, August and December.

We appreciate the efforts of the SHCC and DHSR Staff to arrive at a new Need Methodology for dialysis stations. In general, I believe that the dialysis providers have embraced this new approach. No doubt it has been a challenge to arrive at the current draft plan. Dialysis providers, and their facilities have utilized the Semi-Annual Dialysis Report for greater than 25 years. Obviously this new plan is a tremendous paradigm shift.

I'd like to close my comments with this thought. I live down in Cumberland County, and I normally travel to Raleigh by way of Interstate 95 and Interstate 40. It's about an hour ride from my office to here. Along the way, I cross many bridges, and travel under many more. It never occurs to me that one of these bridges might fail. I've put my faith into the engineers and bridge builders and highway inspectors to ensure that it is safe for me to cross, or go under any and all of these bridges.

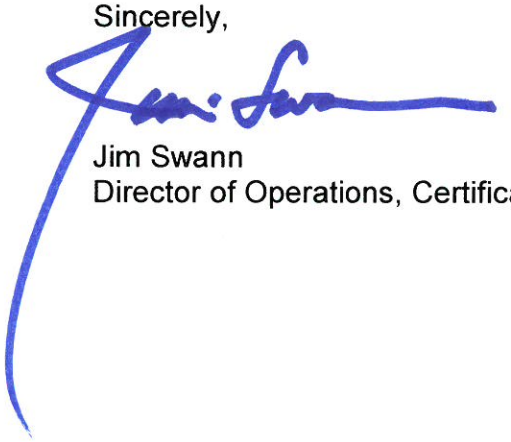
As I noted a moment ago, I'm here on behalf of more than 10,000 dialysis patients. These patients have similarly placed faith into our system of health care planning, to ensure that there are a sufficient number of dialysis stations, in the right place, for them to receive dialysis care. Without saying so, these patients are looking at the SHCC, the DHSR Staff, and the dialysis providers in the same way that each of us who travels the highways has placed our faith into engineers, and bridge builders and highway inspectors.

We have got to get this right. Failure simply is not an option. We cannot fail the patients who depend upon the SHCC, the DHSR Staff and the Providers. Dialysis is not an option. Dialysis patients require regular treatment to sustain life. If we fail to get this correct, then we fail the dialysis patients. When you leave here today, as you drive over any bridge, remember that there are dialysis patients depending on you.

On behalf of Fresenius Medical Care, I look forward to continued dialogue and opportunity to work with the Staff of DHSR Healthcare Planning and Certificate of Need, and the Acute Care Committee of the SHCC. Thank you for the opportunity to share these comments.

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

Sincerely,



Jim Swann
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