FRESENIUS KIDNEY CARE

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March 6, 2019

Dr. Christopher Ullrich, M.D., Chairman
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 2019 State Medical Facilities Plan

Dear Dr. Ullrich and Members of the SHCC:

Good morning. I am Jim Swann, the Director of Certificate of Need for Fresenius Medical Care. I'm here on behalf of Fresenius Medical Care and its related dialysis facilities in North Carolina. Fresenius currently owns, operates, or manages, 115 dialysis facilities across North Carolina. We have another 13 facilities CON approved and at some stage of development.

If I may, and briefly as some background, as of December 31, 2018, Fresenius related facilities in North Carolina were providing dialysis care and treatment to more than 10,000 North Carolina residents. If we count the out of state patients, we were serving more than 10,200 dialysis patients in our facilities within North Carolina.

Dialysis providers, and their facilities have utilized the Semi-Annual Dialysis Report – the SDR as it is commonly known – as the source document for CON applications leading to new dialysis stations and new dialysis facilities since at least 1994. The oldest SDR I have in my office is dated March 1994. So, for at least 25 years we've been using some variation of the current process and methodologies to ensure an adequate inventory of dialysis stations would be available for the ESRD patient population of our state.

About a year ago, Dr. Ullrich mentioned the idea that dialysis needed to be incorporated into the State Medical Facilities Plan, and that the Semi-Annual Dialysis Report should cease to exist. As I understand things, the reasons for the changes are because the SDR is not consistent with the state statutes governing the SMFP, that the SDR is not made available for public comment, and that the Governor has not had the chance to review the information contained in the SDR prior to publication. The SMFP does direct the development of the SDR, and of course the SMFP is reviewed and signed by the Governor. But apparently, for at least the last 25 years, our processes have not been congruent with the state statutes.

I reviewed the March 1994 SDR and note that at the time that SDR was published, there were only 73 dialysis facilities in North Carolina. Furthermore, unlike today where there are only 14 counties without an operational dialysis facility, in 1994, there were 34 counties without a dialysis facility.

As an additional note, that March 1994 SDR reports a total of 5,665 ESRD patients for 1993. Of that number, 1,205, or 21.27% were home dialysis patients. The current SDR reflects 18,295 ESRD patients as of June 30, 2018. Of that number, only 2,353, or 12.86% were home patients.

All to say, in the last 25 years, the growth of the ESRD patient population in North Carolina has more than tripled. At the same time, the percentage of patients doing home dialysis has declined significantly. Consequently more dialysis stations and dialysis facilities have been necessary. Our process, using the SDR, has been working very well to serve the needs of the constantly growing ESRD patient population of North Carolina.

I stand here today to tell you that Fresenius and its related facilities support the concept of a once per year reporting mechanism, through the State Medical Facilities Plan. Our organization filed comments with the DHSR Healthcare Planning and Certificate of Need Office last April, wherein we agreed that this could work, with certain caveats.

Over the past several months, I, along with representatives from other dialysis providers, have met with the Acute Care Committee and members of the Healthcare Planning and Certificate of Need staff to discuss various options, and to work through a couple of proposed methodologies. As the SHCC is sure to know, changing methodologies within the SMFP is no easy task.

Fresenius has one overarching concern: In order to effectively plan, and in order to meet the needs of the growing ESRD patient population in our state, it is imperative that we have the opportunity for every facility to file CON applications twice per year. We have suggested that this happen on a semi-annual basis, and that to the extent that the Healthcare Planning and Certificate of Need Agency have concerns, then requiring a 180 day period of time between CON applications is not unreasonable. But, every facility must have the opportunity to file twice per year.

It is not unknown for a facility to file two applications in a single calendar year under the process we use today. And most certainly, the overwhelming majority of our facilities are not going to qualify to apply twice per year. However, for those that do meet the requirements to file twice in a year, the only way to meet the needs of the patients is to have an opportunity to file the second application.

Members of the SHCC may reasonably ask, "why don't you just file for everything you need in one application?" That's a reasonable question. Growth of the ESRD patient population is not the same in every county in our state. Currently, I believe state wide the ERD patient population is growing at about 3.7% annually. But, if you look at the January 2019 SDR, you will see counties with five year average annual change rates ranging from 14.4% in Washington County, and 13.3% in Alexander County, to lows of negative 4.5% in Lincoln County, and negative 0.8% in Moore County. You'll see numbers of higher magnitude in those counties where there isn't a dialysis facility, for example, Pamlico County has a growth rate of 20.6% and Gates County has a growth rate of 49.5%.

But, in our experience, those facilities which need to file twice per year are generally within the counties with larger ESRD patient populations.

A facility might qualify for only three or four stations in the spring filing. After filing, the growth of the facility census continues, and that same facility that generated a need for three or four stations in the spring, may possibly need another four or five stations in the fall.

My understanding of the purpose of the SHCC is found in Chapter 1 of the SMFP:

> *"The major objective of the Plan is to provide individuals, institutions, state and local government agencies, and community leadership with* ***policies and projections of need*** *to guide local planning for specific health care facilities and services."* [Emphasis added]
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> *"**Chapters dealing with specific facility/service categories contain** summaries of the supply and the utilization of each type of facility or service, a description of any changes in the projection method and policies from the previous planning year, **a description of the projection method, and other data relevant to the projections of need.***
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> *The projections of need for the various facilities and services are used in conjunction with other statutes and rules in reviewing certificate of need applications for establishment, expansion, or conversion of health care facilities and services. All parties interested in health care facility and health services planning should consider this Plan a key resource."*

It is also possible that a facility may qualify for a greater number of stations than it can reasonably project to need. In every application, the applicant must meet the performance standard and applicable CON Review Criteria in order to be approved. I can say that in my experience, there have been multiple occasions where the need methodology generated a greater number of stations than I could prove need for. I say this to say that just because a methodology calculation arising from a once per year report might generate a number of stations for the facility, that facility may only be able prove all of those stations by way of a second CON application six months later, and after the facility patient census has continued increasing.

If I might shift gears slightly now, within out meetings there has been ample discussion around need methodologies, including one suggestion that the SMFP doesn't need to include a specific facility need methodology. Fresenius disagrees and recommends that the SMFP should include a facility need methodology. If I might return to Chapter 1 of the SMFP again, I call you attention to this:

> *"The* ***projections*** *of need for the various facilities and services are used in conjunction with other statutes and rules in reviewing certificate of need applications for establishment, expansion, or conversion of health care facilities and services."* [Emphasis added]

Absent a need methodology, I must ask, how would the SHCC and the CON Agency know what the need might be within a particular facility? Within NC GS 131E-175, Findings of fact, number four says in part:

"(4) That the proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities...."

Fresenius is concerned that the lack of a standard to determine need would lead to a "wild-west" scenario where everything is fair game. Rather, we embrace the well-regulated and controlled environment which has allowed development of dialysis stations and dialysis facilities to support the growing needs of the ESRD patient population in North Carolina.

In closing, if I can leave you with four thoughts:

- Fresenius and its related facilities agrees that the State Medical Facilities Plan can effectively serve as the single source document for planning for dialysis station need, as we have discussed.

- For the SMFP to effectively serve the needs of the growing ESRD patient population in our state, dialysis facilities ***must have*** the opportunity to apply for additional stations twice each year.

- Fresenius and its related facilities support inclusion of a methodology, similar to the historical Facility Need Methodology which has been used by all providers for at least 25 years.

- We strongly believe that the absence of a specific Need Methodology for additional stations in an existing facility could lead to over development of dialysis stations, and underutilization of CON approved healthcare resources.

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
Director of Operations, Certificate of Need