Poyner Spruill LLP

March 23, 2012

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**VIA HAND DELIVERY**

Ms. Nadine Pfeiffer, Branch Manager
Medical Facilities Planning Branch
North Carolina Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Comments by DaVita on Petitions by Fresenius Medical Care

Dear Ms. Pfeiffer:

I am writing on behalf of our client DaVita, whose affiliates operate 62 North Carolina dialysis facilities, to forward the enclosed comments which respond to two petitions to amend the North Carolina State Medical Facilities Plan that were filed by Fresenius Medical Care.

DaVita appreciates this opportunity to provide these comments and looks forward to the opportunity to have further input in any subsequent consideration of these petitions.

With best wishes, I am

Very truly yours,

Bill Shenton

**William R. Shenton**
*Partner*

WRS:klh

Enc.

cc: Craig R. Smith, Chief, CON Section (via hand delivery w/Enc.)

To:

North Carolina State Health Coordinating Council

And

Medical Facilities Planning Section

Division of Health Service Regulation

Department of Health and Human Services

# Response to Fresenius Petition to Amend ESRD Need Methodology

Submitted by:

William L. Hyland

Director of Health Care Planning

DaVita, Inc.

March 23, 2012

## INTRODUCTION

Fresenius Medical Care has proposed several fundamental changes to the long-standing methodology that has been used in North Carolina to project the future need for dialysis stations. This response is offered on behalf of DaVita, Inc. and its North Carolina affiliates, DVA Healthcare Renal Care, Inc., RTC-Mid-Atlantic Treatment Centers, Inc. and Total Renal Care of North Carolina, LLC. Through these three affiliates, DaVita operates 62 dialysis facilities across North Carolina.

The dialysis methodology has been in place since 1993. (See the attached copy of the September 1993 Semi-Annual Dialysis Report.) The changes proposed by Fresenius would significantly limit the development of additional dialysis stations and new facilities by:

- Requiring a minimum of 12 stations, instead of the current 10, to establish a new facility;
- Requiring that before a new facility could be established, all existing facilities in the same county must have a utilization rate of at least 95%;
- Requiring a utilization rate of 95%, rather than the current 80%, to justify an expansion of any dialysis facility.

DaVita categorically opposes each of the changes proposed by Fresenius because they will significantly, and unreasonably, limit the development of new or expanded facilities that are needed on a timely basis. DaVita requests that the State Health Coordinating Council deny the Petition submitted by BMA and refer the dialysis need methodology to an appropriate committee with input from not only dialysis providers but also from dialysis patients and the physicians who provide care for them.

## DETAILED BASIS FOR DAVITA'S OPPOSITION

DaVita's opposition to the Fresenius Petition springs from a number of interrelated factors. First, it is critical to realize the context in which any need standard would be applied to existing facilities that already are serving patients. Taking the example of a Semi-Annual Dialysis Report issued in July of a calendar year, the data contained in that report would be current as of the end of the prior calendar year, on December 31. Thus, under the current methodology, the 95 percent utilization levels proposed by BMA would have to be reached on the prior December 31, and then documented in the July SDR of the next year, in order for a facility to be able to submit an expansion application in September of that next year. After that you have a 120- to 150-day review, followed by a 30-day period during which the law requires that the certificate of need must be held, pending any appeals.

This all means that in a typical scenario when there is no appeal and assuming that a decision is rendered in 150 days, a dialysis facility that meets the target utilization as of December 31 in one year could only anticipate receipt of a certificate of need authorizing an expansion about 15 months later. Then, even after a certificate of need for an expansion is received, there still will be additional time needed to construct or build out space for the additional stations, which can easily add three to

nine more months to the entire process. So the cumulative effect can be a delay of 18 months to almost two years, even without an appeal.

To put all this in concrete terms, a 95% utilization level of a 10-station dialysis facility would equate to 38 patients. So if a facility has a patient census of 38 patients as of December 31 of year one, it would not get a certificate of need to add stations until at least 15 months later and the stations would not be available for another three months. Thus, the only way for this 10-station facility to accommodate more than two additional patients over the entire course of those 18 months would be to add shifts. Of course, a larger facility such as a 20-station facility at 95% utilization would have four openings, it also is certainly more likely that a 20-station facility would be growing at a more rapid rate than most 10-station facilities and so even a four-patient margin in a 20-station facility will be insufficient to provide capacity through the entire 18-month period.

Added to this data lag is another delay for newer facilities, because the SDR's Facility Need Methodology requires every facility to demonstrate its growth over the course of two separate SDRs. This means that a hypothetical recently opened 10-station facility could not apply to add stations based on the first SDR that is issued after it opens. Instead, it would have to wait for a second SDR to be published before it could even apply to expand. So a new facility that achieved a 95 per cent utilization rate in the first SDR that issued on December 31, could not apply in the following September, but would have to wait 15 months, until after the January SDR is issued in the following year to ***even apply***. Even if it had achieved the target utilization as of December of Year 001, it could only submit an application under the January SDR in March of Year 003, so its application would begin review on April 1 of Year 003. Barring an appeal, it could expect to receive a certificate of need six months after applying, or a total of 22 months after it had achieved the target level; and then it could start any necessary construction. This means that for our hypothetical newer facility, the delay from the moment that a utilization threshold is reached to the point in time when additional capacity is available to treat patients would be over two years.

The only alternative for new or established facilities facing a capacity crunch over these lengthy delays is to add dialysis shifts. Although it may be more convenient for a few patients to receive dialysis in a shift that begins in the late afternoon, this is not an ideal option for many. Forcing patients to accept dialysis on a third shift can create significant problems in terms of transportation and family schedules.

Adding shifts also places greater burdens on the physicians and other allied health professionals who furnish care to dialysis patients. The nephrologists and providers who furnish care to dialysis patients typically conduct rounds on patients while they are at the dialysis facility, and adding extra shifts lengthens their work routine. So adding shifts is far from an optimal solution because it leads to higher costs, inefficiency and additional burdens on patients and providers. It is at best an interim stop-gap situation and the Fresenius proposal will greatly exacerbate this problem.

Finally, the Fresenius proposal also will have a significant negative impact on the growth of new facilities in at least two ways. First, by raising both the minimum utilization thresholds to 95 per cent and requiring a minimum size of 12 stations rather than 10, this proposal definitely will limit the number of times that a county need arises under the SDR. The limits also will reduce the ability of existing providers to expand facilities to a sufficient size to allow them to start new facilities by

transfers of stations. This will also limit the widening dispersal and enhanced accessibility to dialysis that has occurred over the past 20 years.

## CONCLUSION

DaVita categorically opposes the Fresenius Petition for the reasons stated in this response. Unless a patient with renal failure is among the lucky few who receive a successful kidney transplant, that patient must receive some form of dialysis to stay alive. Dialysis is a critical part of these patients' health care, and the unquestionable effect of what Fresenius has proposed will be limits on their accessibility to this life-sustaining treatment, adding even more burdens on patients, families and care givers. For all these reasons, the Fresenius proposal does not make sense for dialysis patients or the individuals and organizations that provide their care.

We would welcome the opportunity to participate in further discussion of this important issue, and thank you very much for your consideration of these comments.

William L. Hyland, Director of Healthcare Planning
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2321 W. Morehead Street
Charlotte, NC 28208

To:

North Carolina State Health Coordinating Council

and

Medical Facilities Planning Section

Division of Health Service Regulation

Department of Health and Human Services

# RESPONSE TO FRESENIUS PETITION
# ISOLATION STATION ISSUE

Submitted by:

William L. Hyland

Director of Health Care Planning

DaVita, Inc.

March 23, 2012

Fresenius Medical Care has proposed that isolation stations used for the treatment of dialysis patients who are positive for Hepatitis B should be excluded from the dialysis station inventory. This response is presented on behalf of DaVita, Inc. and its North Carolina affiliates, DVA Healthcare Renal Care, Inc., RTC-Mid-Atlantic Treatment Centers, Inc. and Total Renal Care of North Carolina, LLC. Through these three affiliates, DaVita operates 62 dialysis facilities across North Carolina, and a number of them offer isolation treatments.

DaVita understands and agrees that isolation capability is critical in treating patients who are positive for Hepatitis B. In many remote or rural locations across the state, where there may only be a single conveniently located dialysis facility, it will be essential to have the capability of providing this treatment, without limiting access to services by other dialysis patients. Therefore DaVita believes that the concept proposed by Fresenius has merit and deserves study, but there are at least two issues that merit careful attention in the review of this proposal:

- Any isolation station that a dialysis facility may be authorized by CMS to operate will constitute a part of its capacity by the terms of the Certificate of Need Law. Under the definition of "Bed Capacity" in N.C. Gen. Stat. § 131E-176(2), each dialysis station in a dialysis facility is counted in the facility's bed capacity, and any increase in that bed capacity is an event that requires a Certificate of Need under 131E-176(16)c. Therefore, in order to exclude isolation stations which will be recognized by CMS in the capacity of dialysis facility, from the dialysis station inventory for purposes of the Certificate of Need Law, it is likely that a statutory change will be necessary.

- DaVita also questions whether two isolation stations will be needed in any facility, in view of the data reported by Fresenius which matches the experience of DaVita in this area.

DaVita is ready to participate in any discussion of the issues raised in this Petition and looks forward to the opportunity to do so.

Thank you very much for your attention to these comments.

William L. Hyland, Director of Healthcare Planning
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