



October 31, 2008

Mr. Dayle Stepp  
Director, Certificate of Need  
West Virginia Health Care Authority  
100 Dee Drive  
Charleston, West Virginia 25311

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WV HEALTH CARE  
AUTHORITY

Dear Mr. Stepp:

DaVita appreciates the opportunity to comment on the Health Care Authority's review of the certificate of need ("CON") process for renal dialysis. DaVita provides high quality kidney care for over 200 West Virginians in need of dialysis through our 3 outpatient dialysis facilities located across the state. Nationwide, DaVita operates over 1400 dialysis facilities in 43 states and the District of Columbia. We have the privilege of caring for approximately 110,000 individuals suffering from kidney failure across the United States.

Based on our experience, we believe renal dialysis services should not be subject to CON review in West Virginia. The needs of dialysis patients are unique when compared to other patients suffering from a chronic disease. A person suffering from kidney failure, also known as end-stage renal disease (ESRD), requires either a kidney transplant or frequent dialysis treatments. A typical patient requires a minimum of three treatments per week for approximately 3-4 hours at a time. Primarily, these treatments are performed in an outpatient setting which requires the patient to travel.

The intensity and invasive nature of dialysis treatment leaves many patients in a weakened state, and as such, they typically rely on family members or some form of public transportation to deliver them to and from the facility. Because of this, proximity to a patient's residence is an important consideration for patients and their treating physicians when selecting a dialysis provider. Local access to care is critically important.

Due to the frequency and duration of treatment, a dialysis patient's caregiver team is vitally important, both in terms of quality of care and quality of life for the patient. The dialysis facility becomes the patient's "second home" and often times their caregivers are like family. Finding an environment in which the patient feels comfortable is critically important. The more options a patient has in determining where to dialyze, the better. To be clear, not all dialysis providers are alike. As a company, DaVita significantly exceeds national averages with regard to patient quality, as validated by both the Clinical Performance Measures Report published in 2006 by the Centers for Medicare and Medicaid Services (CMS), and the December 2007 Fistula First Vascular Access Improvement Initiative. Outcomes data confirms that the risk of mortality faced by patients dialyzed at DaVita facilities may be as much as 8% lower than the national average. DaVita consistently surpasses national averages for CMS CPM and KDOQI outcomes. Most recently, DaVita outperformed the national averages by as much as 44% on four key clinical performance outcomes<sup>1,2</sup>.

The state should encourage the development and availability of multiple providers for West Virginians in need of dialysis services. A repeal of CON review for renal dialysis would give dialysis patients and their families across the state more choices and competition would foster

1DaVita Inc., Q1 2008; 22006 CMS Clinical Performance Measures Report (most recently published data; results from 2005 calendar year);

2Fistula First National Vascular Access Improvement Initiative Website ([www.fistulafirst.org](http://www.fistulafirst.org)), results from December 2007;

3West Virginia Department of Health and Human Resources Report: The Impact of Chronic Kidney Disease in West Virginia; April 2006, pg. IV

high-quality care and the development of state-of-the-art facilities that are convenient and responsive to patients' needs.

Unfortunately, the need for dialysis services is only increasing. The two leading causes of kidney failure are diabetes and hypertension. With trends in these areas rising steadily in West Virginia and nationwide, access to kidney dialysis services will be vital for West Virginians in need of dialysis, both today and in the future. According to data from the United States Renal Data System, West Virginia's rate of ESRD incidence (new cases per year) was consistently higher than the national rate from 1994-2003. Both ESRD incidence and prevalence (all living ESRD patients) among patients with diabetes have risen at a faster rate in the state than in the nation over the 10-year period<sup>3</sup>.

We do not believe that a proliferation of facilities will result if the CON requirements are repealed. Dialysis treatment is unique in that it is non-optional and based on patient need, not something that could be "overutilized" as with some specialty services. Additionally, DaVita takes exhaustive measures to assess community need prior to constructing a new facility. It analyzes the present and future need in the area, existing capacity, and long-term financial solvency for a proposed facility. Due to the uniqueness of the ESRD benefit in Medicare, upwards of 80% of all dialysis patients utilize a government program to pay for their care. This distinctive fact drives the economics of the dialysis industry and dictates that dialysis providers, both large and small, undertake the appropriate considerations to ensure that each facility is financially viable for the long term. Additionally, it should be noted that creation of a new

<sup>1</sup>DaVita Inc., Q1 2008; 22006 CMS Clinical Performance Measures Report (most recently published data; results from 2005 calendar year);

<sup>2</sup>Fistula First National Vascular Access Improvement Initiative Website ([www.fistulafirst.org](http://www.fistulafirst.org)), results from December 2007;

<sup>3</sup>West Virginia Department of Health and Human Resources Report: The Impact of Chronic Kidney Disease in West Virginia; April 2006, pg. IV

dialysis facility does not create a need for any additional funding from the state. The risk lies squarely on the clinic owner.

In fact, a repeal of CON requirements for renal dialysis facilities would have an economic benefit for the state. Approximately 30-40% of patients nationally are dually eligible for Medicare and Medicaid, meaning they qualify for non-emergency medical transportation offered by many Medicaid programs. The repeal of CON requirements for renal dialysis, and the subsequent creation of new dialysis facilities throughout the state, could potentially save the state money as the need for transporting dialysis patients to and from treatment over long distances is reduced. Secondly, although modest, the opening of new dialysis facilities in traditionally underserved areas of West Virginia, or areas that do not have a facility at all, is a source of local jobs in the growing health care sector. Finally, it has been observed that many dialysis providers build centers and service West Virginia patients just across state lines in order to avoid the CON requirement. This obviously violates the goals of the state's certificate of need program, and potentially represents a loss of potential tax revenue for the state.

If the Authority decides not to recommend a repeal of the CON requirements, we offer one change that would limit unnecessary duplication of services. That change would be to require applicants for a new facility to conduct an assessment of existing facilities in the service area to determine whether they are operating at full capacity or are willing to increase capacity. This change would allow existing providers the opportunity to meet the needs of the communities they serve without the additional expense of developing a new facility.

<sup>1</sup>DaVita Inc., Q1 2008; 22006 CMS Clinical Performance Measures Report (most recently published data; results from 2005 calendar year);

<sup>2</sup>Fistula First National Vascular Access Improvement Initiative Website ([www.fistulafirst.org](http://www.fistulafirst.org)), results from December 2007;

<sup>3</sup>West Virginia Department of Health and Human Resources Report: The Impact of Chronic Kidney Disease in West Virginia; April 2006, pg. IV

It is our belief that CON review is no longer necessary for renal dialysis services because of the unique dynamics within the dialysis industry, a growing need for dialysis services in the state, and the need to encourage high-quality care and more choice for West Virginians. Again, we thank you for the opportunity to comment, and we respectfully request that the Health Care Authority recommend removing renal dialysis from CON review.

Sincerely,

A handwritten signature in blue ink that reads "Tom Purkins". The signature is written in a cursive, flowing style.

Tom Purkins  
Divisional Vice President  
DaVita, Inc.

<sup>1</sup>DaVita Inc., Q1 2008; 22006 CMS Clinical Performance Measures Report (most recently published data; results from 2005 calendar year);

<sup>2</sup>Fistula First National Vascular Access Improvement Initiative Website ([www.fistulafirst.org](http://www.fistulafirst.org)), results from December 2007;

<sup>3</sup>West Virginia Department of Health and Human Resources Report: The Impact of Chronic Kidney Disease in West Virginia; April 2006, pg. IV