Constantino, Mike

From: Clare.Ranalli@hklaw.com
Sent: Friday, August 05, 2011 1:34 PM
To: Constantino, Mike
Cc: Avery, Courtney; Lori.Wright@fmc-na.com; Julie.Hawkins@fmc-na.com
Attachments: Response to Claims in U S Renal Applications.PDF

Hi Mike -

Attached is the letter we discussed earlier today. Please place one in each of the US Renal application records. Also, if you need a hard copy let me know. As always, thank you.

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August 5, 2011

Dale Galassie, Chairman
Illinois Health Facilities and Services Review Board
525 W. Jefferson Street, Second Floor
Springfield, Illinois 62761

Re: Response to Repeated False and/or Misleading Claims in U.S. Renal Application Nos. 11-024, 11-025 and 11-026

Dear Mr. Galassie:

Fresenius Medical Care believes it is important to correct false and untrue statements contained in U.S. Renal Care applications referenced above. Fresenius is particularly compelled to do so because the misleading statements made are to induce the Board to approve the U.S. Renal applications.

Claim One: Fresenius delays admissions to its facilities increasing health care costs. Fresenius does not intentionally, systematically or otherwise delay admission to its facilities, and works diligently to facilitate admission. Physician letters that have been and will be submitted refute U.S. Renal Care's claim that Fresenius impedes admissions from hospitals to its clinics. Like all dialysis facilities, Fresenius must comply with CMS Conditions for Coverage, which require it to have certain information and documentation such as having a recent Hepatitis B screening, prior to admission, and this can result in occasional delays. However, U.S. Renal focuses on a few discharges from a hospital to a clinic involving acute patients (those who experience renal failure unexpectedly), which represent a small number of in center hemodialysis admissions, to make misleading conclusions that there is a pervasive and constant issue.

Claim Two: Fresenius severely limits access due to its admission policies. This claim is based on three patients who allegedly were denied admission because they have catheters (versus AVF access) for dialysis. Fresenius facilities do not restrict admission of patients with catheters. In fact, the physicians supporting U.S. Renal's applications have patients with catheters in the very facility (Bolingbrook) they claim denies admission to patients on this basis. Fresenius does follow generally accepted standards of care in promoting accesses other than via catheters as catheters are associated with increased hospitalization and poor patient outcomes, as opposed to

other types of accesses (see attached) – but it does not deny admission based on a patient's access.

Claim Three: Fresenius has a monopoly. U.S. Renal's claims of market dominance are not relevant to the Board's review criteria and jurisdiction, and are designed solely to pander to emotion. Fresenius is the largest provider of dialysis services in the United States. However, use of the word monopoly connotes bad or even illegal activity, and diverts focus from the fact Fresenius provides access to dialysis throughout the State (including rural and inner city areas), does not have restrictive patient admission policies, and has open staffing for all qualified nephrologists.

The Illinois residents who require dialysis are individuals facing a health crisis. They deserve both reasonable access to care and continuity of care with their physician. The Board should analyze U.S. Renal's applications vis-à-vis the Board's review criteria to determine the eligibility and fitness of the provider, the need for the facility at issue, the quality of care and the cost associated with the proposed facility. U.S. Renal has chosen to question Fresenius' operations to divert focus from those criteria.

Thank you for your consideration.

Sincerely yours,

HOLLAND & KNIGHT LLP

Clare Connor Ranalli

CCR/mjy
Enclosure

cc: Courtney Avery
Mike Constantino
Lori Wright
Julie Hawkins

The Gold Standard

arteriovenous FISTULA FIRST

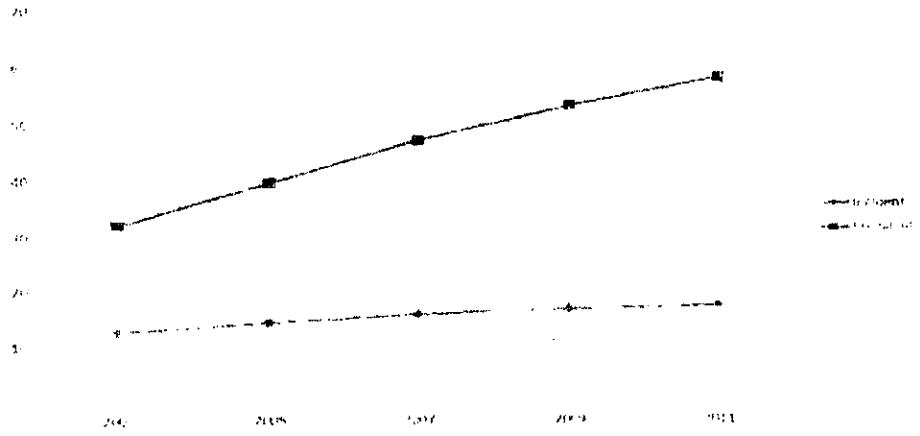


Figure 1. Incident & prevalent AVF rates since the launch of the FFBI

A Message from the FFBI Nephrology Consultant

The Fistula First Breakthrough Initiative (FFBI) has continued its momentum and success into 2011. The national prevalent arteriovenous fistula (AVF) use rate rose to 57.9% in March 2011, and 17 of 18 ESRD Networks achieved their respective goals for increasing AVF use in their geographic areas during the 2010-2011 contract cycle. This phenomenal vascular access culture change in the United States is due to the commitment of all national and local stakeholders to fundamentally change the way they care for patients approaching and receiving hemodialysis.

A central venous catheter is no longer a path of least resistance; it is appropriately viewed as a toxic state which, in most cases, should be eliminated as soon as possible. A better understanding of the appropriate milestones for AVF maturation – and timely intervention if those milestones are not met -- has prevented an increase in long-term catheter use despite the 25% increase in AVF prevalence since the beginnings of the FFBI (then known as the National Vascual Access Improvement Initiative) in 2003. Most of the increase in AVF prevalence since 2003 has also been mirrored by an associated decrease in arteriovenous graft (AVG) prevalence. These trends constitute positive momentum, but there remain opportunities for further improvement as we continue to strive towards achieving the national AVF prevalence goal of 66%.

Major challenges for the future include determining which patients have a poor outlook for AVF success and therefore should undergo AVG placement as their first permanent access, which patients with non-maturing AVFs should undergo further procedures, additional wait time or should undergo AVG placement, and how to decrease the abysmal incident 80% incident catheter rate, which will involve greater engagement by referring physicians and hospital systems.

The 25% increase in prevalent AVFs since 2003 is most impressive and a source of pride for the dialysis community. However, there is plenty of work to be done in providing the best vascular access for all hemodialysis patients in the timeliest manner. The FFBI looks forward to continuing its role as a think tank for vascular access innovation and a clearing house for best practices. J , Wish, MD

This material was prepared by the End Stage Renal Disease Network Coordinating Center, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services CMS Contract Number HHSM-500-2010-NW002C

Hemodialysis Vascular Access

Hemodialysis cleans your blood through a fistula, graft or catheter. One of these will be your hemodialysis **LIFELINE!**

Talk with your doctor to decide which type of vascular access is best for you.

Fistula

A fistula directly connects an artery to a vein. The vein stretches over time, allowing needles to be put in it. **Fistulas are the best way to get access to the bloodstream for hemodialysis.**

Advantages

- Permanent
- Beneath the skin
- Lasts longest, up to 20 years
- Provides greater blood flow for better treatment
- Fewer infections & other complications
- Fewer hospitalizations
- Better survival (lower risk of dying than patients with catheters)

Disadvantages

- May not mature/develop
- Not possible for all patients
- Usually cannot be used for at least 6-8 weeks

Graft

A graft is a tube, usually made of plastic, that connects an artery to a vein, allowing needles to be put in it. Grafts are the second best way to get access to the bloodstream for hemodialysis.

Advantages

- Permanent
- Beneath the skin
- May be used after 2 weeks, in some cases
- May work in patients with poor veins

Disadvantages

- Increased hospitalizations
- Increased risk for clotting
- Increased risk for serious infections
- Increased risk for other complications and repair procedures
- Does not last as long as a fistula

Catheter

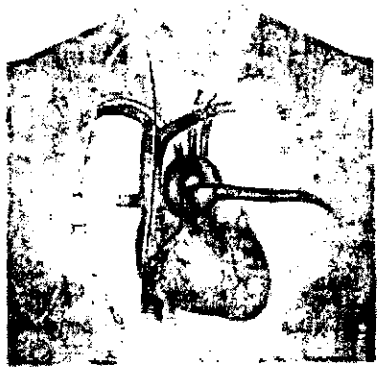
A catheter is a tube inserted into a vein in the neck or chest to provide vascular access for hemodialysis. The tip rests in your heart. It is usually a **temporary** access. It is the third choice for getting access to the bloodstream for hemodialysis. For some patients it is the only choice and it will need to be used as a permanent access.

Advantage

- Can be used immediately after placement

Disadvantages

- Higher infection rates, which can be very serious or fatal
- Increased hospitalizations
- Does not last long, usually less than one year
- May require longer treatment times
- Prolonged use may lead to inadequate dialysis
- Cannot shower without special appliance
- High rate of clotting requiring frequent procedures
- Risk of destroying important veins



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Adapted with modifications from a flyer produced by the Roanoke Vascular Access Center, 4/10. *This material was prepared by the Mid-Atlantic Renal Coalition as part of the Fistula First Breakthrough Initiative Special Project, which is performed under contract HHSM 500-2006-NW005C, with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy.*