



**Fresenius Medical Care**

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WV HEALTH CARE  
AUTHORITY

October 29, 2008

Sonia Chambers, Chair  
West Virginia Health Care Authority  
100 Dee Drive  
Charleston, West Virginia 25311

RE: End Stage Renal Disease Certificate of Need Standard  
Bio-Medical Applications of West Virginia, Inc.

Ms. Chambers:

Bio-Medical Applications of West Virginia, Inc. ("BMA") thanks you for the opportunity to provide written comments following the public meeting held on September 25, 2008. The West Virginia Health Care Authority asked those attending the public meeting to submit written recommendations and comments regarding the current End Stage Renal Disease Certificate of Need Standards ("ESRD Standards") approved by the Governor on October 5, 1992.

BMA and its parent organization, Fresenius Medical Care, is a national provider of dialysis services. Currently, BMA provides in-center and home dialysis services to patients throughout West Virginia. BMA currently operates 16 dialysis facilities located throughout West Virginia. Also, BMA has received certificate of need approval and is currently developing four additional facilities located in Kanawha County, Cabell County, Wyoming County and Greenbrier County.

According to the Mid-Atlantic Regional Coalition ("MARC") data, as of August 29, 2008, there are currently approximately 1,782 dialysis patients in West Virginia. Pursuant to the MARC data as of December 31, 2007, there are currently 226 home dialysis patients and 1,581 in-center dialysis patients.

Based on BMA's statistics and review there are a total of 28 dialysis facilities located in West Virginia. Out of a total of 55 West Virginia counties, 25 of those counties have at least one dialysis facility located within the county (this statistic includes approved but not yet developed facilities). Approximately 71% of the dialysis patients statewide live in 17 West Virginia counties. Eight West Virginia counties without a dialysis facility have at least 20 dialysis patients and 24 West Virginia counties have fewer than 20 dialysis patients. BMA estimates that approximately 364 dialysis patients now travel to another county for dialysis treatment.

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BMA supports the continued review and oversight of dialysis services in West Virginia by the Authority. The certificate of need process in West Virginia has worked well to allow for a balanced health planning approach to meet the dialysis needs of West Virginians. Generally, the certificate of need process requires anyone interested in developing a new facility to go through a thoughtful process to determine whether there is a need for the service in the particular area, whether the projected need allows the proposed facility to be financially feasible and requires the proposed facility to be federally certified and meet required standards for quality.

Deregulation of dialysis in West Virginia, by removing dialysis services from the list of reviewable certificate of need services, will not have a positive impact on the level of services provided to dialysis patients in West Virginia. The deregulation may cause additional facilities to be developed in counties with a high number of dialysis patients where current facilities are providing quality services at a level that is economical and financially feasible. Introducing additional facilities in these counties that are already adequately providing services to the patient population will not impact the cost of such services because of the highly regulated system of payment for dialysis services. As discussed at the public meeting, the majority of dialysis services are paid for by governmental providers and thus deregulation has little impact on the cost of services.

Although BMA recommends and supports continuing the certificate of need review requirements for dialysis services, it does not support using the current need methodology set out in the ESRD Standards approved by the Governor in 1992. The ESRD Standards should be reviewed and updated by the Authority to reflect a more current approach to the health planning for dialysis services in West Virginia. By updating the ESRD Standards, the Authority can help to facilitate providers in West Virginia maintaining high quality dialysis services, provide incentives for potential dialysis providers to locate facilities in areas of the state that will provide greater access to services and strengthen the overall dialysis service network of providers in West Virginia.

BMA supports moving forward with updating the current ESRD Standards. BMA will participate and provide its experience in helping to develop updated ESRD Standards focused on improving the overall dialysis services in West Virginia. To begin the process of updating the current standards, BMA offers the following initial comments.

The current need methodology under the ESRD Standards presumes a need for the services if the proposed provider can meet the federal guidelines and Medicare certification for dialysis facilities. The Authority should revise the need methodology standards to lead providers into underserved areas to provide better access and reduce drive times for dialysis patients. Currently, approximately half the counties in West Virginia do not have a dialysis facility within the county, resulting in more than 20% of the patient population traveling out of county for their three weekly dialysis treatments. Specifically, the Authority may want to consider modifying the need methodology as follows.

- a. **Service Areas:** The Authority should consider defining the service area by county boundary. In areas with small ESRD patient populations, a service area may be defined as two or more specified counties.

- b. **Need Methodology (In-Center):** In-Center hemodialysis is the predominant modality in West Virginia (and nationwide). In West Virginia, approximately 85% of the ESRD patients receive dialysis in a traditional In-Center setting. As noted above approximately 20% of these patients are traveling out of county for dialysis treatment. The Authority should consider the following in updating the ESRD Standards:
1. The dialysis facility should have a minimum of twelve (12) dialysis stations. A 12 station facility could provide treatment for up to 48 patients on traditional dialysis patient shifts.
  2. A provider must demonstrate that the facility is projected to provide treatment for a minimum of 36 dialysis patients (75% capacity) at the end of the first year of operations after the facility is certified.
  3. In order to apply for a new ESRD treatment facility, all other dialysis facilities within the service area must be operating at 75% capacity.
  4. If there is not a sufficient patient population, or projected patient population to be served, within the county, two or more counties may be combined to satisfy the need. In this case, the combined counties may not have a dialysis facility operating at less than 75% capacity.
  5. An existing dialysis facility may apply for a certificate of need to add additional dialysis stations. The applicant must demonstrate that the facility is projected to be operating at 75% capacity at the end of the first year after the new stations are certified.
  6. The Authority recognizes that some patients may require treatment in a separation room consistent with CDC recommendations for patients who are Hepatitis B positive. The separation station should not be included in the facility complement of In-Center dialysis stations for purposes of calculating 75% capacity.
- c. **Need Methodology (Home Dialysis):** Currently, approximately 15% of the ESRD patient population receives dialysis in the home setting. The Authority should consider exempting from review a certified facility offering home therapies (i.e., home peritoneal dialysis or home hemodialysis). The addition or offering of home therapies by an existing certified provider should not be subject to certificate of need review and should only require certification by OHFLAC. The establishment of any new stand alone home dialysis program should require certificate of need review and approval. The Authority could utilize the existing need methodology (demonstrating Medicare certification) as the basis to establish a new home dialysis program.

Also, the ESRD Standards should continue to have components requiring the applicant to address quality, continuum of care, financial feasibility and accessibility.

In conclusion, again BMA appreciates the opportunity to participate in the process to review the current certificate of need standards for dialysis facilities. As we continue to review the current standards and any written comments filed by others we will supplement this initial response.

If you have any questions or want additional information that we can provide, please do not hesitate to contact us.

Very truly yours,

A handwritten signature in cursive script, appearing to read "Debbie Frazier".

Debbie Frazier  
Regional Vice President  
West Virginia/Eastern Kentucky