



North Carolina Department of Health and Human Services
Division of Health Service Regulation

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Governor

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Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

January 10, 2013

Jim Swann
3717 National Drive, Suite 206
Raleigh, NC 27612

RE: No Review / Bio-Medical Applications of North Carolina d/b/a FMC Warren Hills / Addition of home dialysis therapies -home hemo-dialysis training and home peritoneal dialysis training and follow-up to existing certified hemodialysis stations for which a certificate of need was issued / Warren County

Dear Mr. Swann:

The Certificate of Need (CON) Section received your letter December 5, 2012 regarding the above referenced proposal. The proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need provided that the addition of home hemo-dialysis and home peritoneal dialysis training and follow-up does not result in the development of hemo-dialysis or peritoneal dialysis training stations that are in addition to the twenty-five current dialysis stations stated in the scope of the certificate of need for the facility. Further, it should be noted that the Acute and Home Care Licensure and Certification Section is responsible for counting the number of dialysis stations developed in a facility as part of their survey process. It is our understanding that the surveyors count the total number of stations located in the facility not the number of stations in use in the facility at any given time.

At this time, the CON Section has authorized Bio-Medical Applications of North Carolina d/b/a Fresenius Medical Care Warren to develop home-hemodialysis training and home peritoneal dialysis training and follow-up without a change in the number of certified stations. In other words the total number of "stations" (i.e. home hemo-dialysis training and home peritoneal training plus hemodialysis) reported on line 22 of Form CMS-3427 may not exceed twenty-five dialysis stations, the total number of stations that is stated in the scope of the certificate of need for this facility.

In addition, you should contact the Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project. Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D. # (FID).

www.ncdhhs.gov • <http://www.ncdhhs.gov/dhsr>

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Location: Edgerton Building, 809 Ruggles Drive • Raleigh, NC 27603

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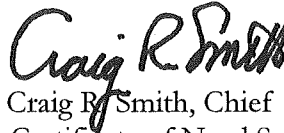
An Equal Opportunity/ Affirmative Action Employer



Sincerely,



F. Gene DePorter, Project Analyst
Certificate of Need Section



Craig R. Smith, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHR
Acute and Home Care Licensure and Certification Section, DHR



**FRESENIUS
MEDICAL CARE**

Done

December 5, 2012

Mr. Craig R. Smith, Chief
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, N.C. 27603



Re: Request for No Review Determination, FMC Warren Hills, add Home Therapies

Dear Mr. Smith:

BMA requests a No Review Determination which will allow FMC Warren Hills to add home training and support for both Peritoneal Dialysis and Home Hemo-dialysis services. BMA has received numerous requests for the addition for home therapies at the FMC Warren Hills facility from admitting physicians and patients. The July 2012 SDR reports only two dialysis patients of Warren County are home patients. Thus, only 3.34% of the ESRD patient population of Warren County are home patients. Contrast this with a statewide average of 11.61%. The addition of home therapies at FMC Warren Hills will offer more options for localized home training and will likely lead to more patients dialyzing at home.

BMA seeks to convert one in-center station for the provision of home hemo-dialysis training and support. This station will be dedicated exclusively to the provision of home hemo-dialysis training and support. As a consequence of this change, the facility will have 24 in-center dialysis stations.

In addition BMA also seeks to add Peritoneal Dialysis training and support to the facility. The addition of Peritoneal Dialysis will not involve utilization of a dialysis stations.

BMA requests that your office approve the addition of this service without further need for CON review. If you have any questions regarding these comments, please contact me at 919.896.7230, or via email, jim.swann@fmc-na.com.

Respectfully,

Jim Swann, Director
Market Development and Certificate of Need

Market Development and Certificate of Need

3717 National Drive, Suite 206
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