



North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section

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March 20, 2012

Jim Swann
Director, Market Development and Certificate of Need
Fresenius Medical Care
3725 National Drive, Suite 130
Raleigh NC 27612

RE: No Review/ BMA Albemarle/ Provision of home hemodialysis training services utilizing one of 22 existing certified hemodialysis stations for which a certificate of need was issued April 28, 2008 / Stanly County FID # 755784

Dear Mr. Swann:

The Certificate of Need (CON) Section received your letter of January 13, 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 dialysis training services does not result in the development of hemodialysis training stations that are in addition to the total number of 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 BMA Albemarle to develop a total of no more than 22 hemodialysis stations, of which one may be used for hemodialysis training. Thus, the facility may not have 22 hemodialysis stations, plus one additional hemodialysis training station. In other words, the total number of "stations" (i.e. hemodialysis training plus hemodialysis) reported on line 22 of Form CMS-3427 may not exceed the total number of dialysis 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.# 755784.

Sincerely,

Paula Quirin, Project Analyst
Certificate of Need Section

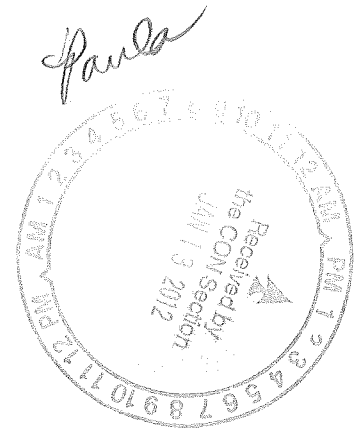
Craig R. Smith, Chief
Certificate of Need Section

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





Fresenius Medical Care



January 13, 2012

Mr. Craig R. Smith, Chief
Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Request for No Review Determination, Add Home Therapies, Home Hemo-Dialysis and Peritoneal Dialysis at BMA Albemarle Dialysis facility, Provider # 34-2565

Dear Mr. Smith:

BMA seeks a No Review Determination to add home dialysis therapies, home hemo-dialysis and peritoneal dialysis, to BMA Albemarle in Albemarle, Stanly County. BMA Albemarle is currently certified for 22 dialysis stations. We propose to operate the 22 stations as 21 In-Center dialysis stations and one home hemo-dialysis training stations, and to also add home peritoneal dialysis training and support...

In recent months the interest in home hemo-dialysis training has significantly increased. The nephrology physicians and patients at BMA Albemarle are requesting more opportunities for home training for home hemo-dialysis. At present the BMA Albemarle facility is not certified for the provision of home dialysis training and support. Consequently, patients desiring home dialysis must travel out of county for training. BMA believes it is appropriate to realign the stations within the facility. The following information is provided in support of this request.

BMA seeks to operate one Home Hemo-dialysis training station. Home Training involves the patient coming to the facility and receiving hemodialysis in an environment which as much as possible emulates the home environment. In this case, BMA will dedicate a training room to home hemo-dialysis training.

The water connections are typical for the home environment, such as kitchen or bathroom connections. The water connections are not a part of the In-Center hemo-dialysis supply system; the In-Center solution delivery system is not connected in any manner. The drains used in home dialysis are typical for home sink drainage.

The patient and home partner are taught the concepts of dialysis, equipment operations, supply ordering, and all aspects of the dialysis treatment to include cannulation (the needle stick). Patient safety issues are also thoroughly trained. The patient is also taught about emergency procedures such as power failures and "needle-stick" issues.

In short, the patient is taught to self administer the same hemodialysis treatment that would otherwise be delivered in a traditional In-Center dialysis setting. The difference of course is that this treatment will be performed by the patient at home.

BMA will also add Peritoneal Dialysis training at the facility. Much as in the home hemodialysis discussion above, BMA will convert existing space into a home PD training room.

Once the Home Training RN is assured that the patient can safely perform training in the home, the patient will begin home dialysis. This training normally involves several weeks and is dependent upon the patient ability. Subsequent to the patient beginning dialysis at home, the patient will normally return to the Home Training clinic on a monthly basis for routine follow-up and lab draws.

Each patient performing home dialysis is provided with a call in phone number to speak with an RN trained in Home Dialysis. This RN is able to provide advice and guidance on the full gamut of home dialysis to include technical issues, safety issues, supply issues, etc.

I trust that the above information will allow you to quickly approve this request. I look forward to receipt of your approved No Review Determination. If you have any additional questions please contact me at 919-896-7230, or email jim.swann@fmc-na.com.

Sincerely,



Jim Swann
Director, Market Development and Certificate of Need

Cc: Azzie Conley, Chief, DHSR/Licensure and Certification