



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

2704 Mail Service Center • Raleigh, North Carolina 27699-2704
<http://www.ncdhhs.gov/dhsr/>

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor
Albert A. Delia, Acting Secretary

Craig R. Smith, Section Chief
Phone: (919) 855-3873
Fax: (919) 733-8139

March 1, 2012

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

RE: No Review / Addition of Home Hemo-Dialysis therapy to existing dialysis facility / Scotland County

Dear Mr. Swann:

The Certificate of Need (CON) Section received your letter of January 13, 2012 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section.

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) if the facility is licensed.

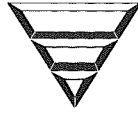
Sincerely,

Tanya S. Rupp, Project Analyst

Craig R. Smith, Chief
Certificate of Need Section

cc: Acute and Home Care Licensure and Certification Section, DHSR

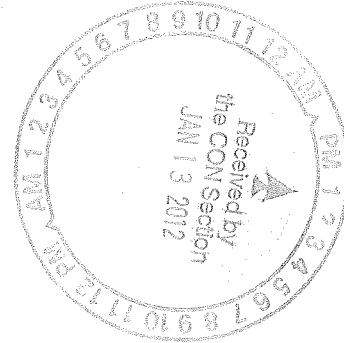




Fresenius Medical Care

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 Hemo-Dialysis BMA Laurinburg
Dialysis facility, Provider # 34-2540

Dear Mr. Smith:

BMA seeks a No Review Determination to add home hemo-dialysis therapy to BMA Laurinburg in Laurinburg, Scotland County. BMA Laurinburg is currently certified for 26 dialysis stations. We propose to operate the 26 stations as 25 In-Center dialysis stations and one home hemo-dialysis training station. The facility certification currently includes 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 Laurinburg are requesting more opportunities for home training for home hemo-dialysis. At present the BMA Laurinburg facility is not certified for the provision of home hemo-dialysis training and support. Consequently, patients desiring home hemo-dialysis must travel to Lumberton or Fayetteville 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.

Once the Home Training RN is assured that the patient can safely perform dialysis 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