

PETITION

Submitted to the

North Carolina State Health Coordinating Council
Medical Facilities Planning Section
Division of Health Service Regulation
Department of Health and Human Services

Petition to Amend
ESRD Need Methodology
Exclude Isolation/Separation Statons

Submitted by:

Fresenius Medical Care
Jim Swann
Director, Market Development and Certificate of Need

March 6, 2012

DFS Health Planning
RECEIVED

MAR 06 2012

Medical Facilities
Planning Section

Petition to Amend ESRD Need Methodology

Submitted by: Jim Swann, Director, Market Development and Certificate of Need
Fresenius Medical Care-NA
3725 National Drive, Suite 130
Raleigh, N.C. 27612

Phone: 919-896-7230
Fax: 919-896-7233
Cell: 919-397-5699
Email: jim.swann@fmc-na.com

Submitted on: March 6, 2012

Submitted at: DHSR/Medical Facilities Planning Section

Submitted to: Nadine Pfeiffer, Interim Branch Manager
Medical Facilities Planning Section
809 Ruggles Drive
Raleigh, N.C. 27603

Long-Term and Behavioral Health Committee
N.C. State Health Coordinating Council

- Mr. Jerry Parks, Chair
- Dr. Thomas Pulliam, Vice Chair
- Mr. Donald Beaver
- Mr. Johnnie Farmer
- Senator Anthony Foriest
- Mr. Ted Griffin
- Ms. Frances Mauney
- Mr. Zach Miller
- Ms. Pam Tidwell

CC: DHSR/CON Section, Mr. Craig R. Smith, Chief

Petition to Amend ESRD Need Methodology

Petitioner Contact Information

Petitioner is Fresenius Medical Care-North America (FMC). FMC is the leading provider of dialysis services within North Carolina, operating dialysis facilities in 85 facilities in 43 North Carolina Counties (includes our affiliations with Renal Research Institute facilities / Carolina Dialysis, LLC). FMC is generally known as:

Bio-Medical Applications of North Carolina, Inc
Bio-Medical Applications of Fayetteville, Inc
Bio-Medical Applications of Clinton, Inc.

In addition to the BMA facilities, FMC also has ownership interest in the Carolina Dialysis, LLC, dialysis facilities which are jointly owned and operated by the University of North Carolina at Chapel Hill.

The local FMC point of contact is:

Jim Swann, Director, Market Development and Certificate of Need
Fresenius Medical Care-NA
3725 National Drive, Suite 130
Raleigh, N.C. 27612

Phone: 919-896-7230
Fax: 919-896-7233
Cell: 919-397-5699
Email: jim.swann@fmc-na.com

Jim is our CON specialist and has filed more than 200 CON applications in the most recent eight years. He is well versed in current need methodologies. Jim is available to the SHCC as a resource throughout your considerations of this petition.

Statement of the requested adjustment

FMC proposes that isolation (separation) stations be excluded from the dialysis station inventory.

Further FMC proposes that existing and approved dialysis facilities should be allowed to develop isolation stations outside the scope of the Certificate of Need. FMC proposes that current providers with less than 31 dialysis stations (30 or fewer certified stations) should be afforded one (1) isolation station. Providers with more than 30 dialysis stations should be afforded two (2) isolation stations.

FMC proposes that the Division of Health Service Regulation compile a data base of all existing and approved dialysis providers and determine the number of isolation stations currently available in North Carolina. This information should be reported as a new Table C within the Semiannual Dialysis Report (SDR).

Reasons for the requested adjustment

The need for isolation/separation stations is very low:

- The Centers for Disease Control has established the standard of care for ESRD patients positive for Hepatitis B. Hepatitis B positive patients must be dialyzed within a separate area to minimize the risk of spreading the hepatitis virus.
- The number of ESRD patients positive for Hepatitis B is nominal. A 2002 national survey of chronic hemodialysis centers reveal the prevalence of hepatitis B surface antigen (HBsAg) positivity among U.S. dialysis patients was approximately 1%. See Attachment 1, page 3 (highlighted text).
- The January 2012 SDR reports a total of 14,455 dialysis patients residing in North Carolina. Using the national average of 1%, it is reasonable to conclude that as many as 145 ESRD patients residing in North Carolina are positive for hepatitis B.
- As noted within the introduction to this petition, FMC is the leading provider of dialysis services in North Carolina. Information within the January 2012 SDR indicates that FMC currently operates 85 dialysis facilities across the State. These facilities included 2,198 dialysis stations, serving 6,770 dialysis patients.
- FMC has surveyed its facilities and reports that of the 6,770 dialysis patients being treated at FMC facilities, only 27 of these patients were hepatitis B positive. This is less than 0.5% of the patients served by FMC.
- Under the current utilization guidelines (FMC has submitted a separate Petition to change the existing ESRD methodology) a single dialysis station will normally be expected to provide treatment for four dialysis patients.
- However, CMS guidelines now require new dialysis facilities to develop an isolation station capability, or to seek a waiver if the patient can be referred to another nearby facility. However, no guidelines have been established for such waivers.

- Generally, in North Carolina new dialysis facilities are 10 stations. This is especially true when one considers new facilities arising from County Need Determinations, i.e., Davie County, 2008; Alexander County 2009; Randolph County, 2010; Northampton County, 2011. In each of the foregoing, the CON applicant proposed to develop a new 10 station dialysis facility with isolation station. That isolation station represented 10% of the identified need. Thus, 10% of the identified station need was dedicated to only 1% of the population. As a consequence, a severe imbalance of stations dedicated to isolation has been created.
- Moreover, once a single hepatitis B positive patient begins to dialyze on the isolation station, that station can not be used for the general dialysis patient population. See Attachment 2, pg 6. Dialysis stations/machines used to provide dialysis for hepatitis B positive patients should only be used for other hepatitis B positive patients.
- In FMC experience across North Carolina, it is rare to have multiple hepatitis B positive patients at a single dialysis facility. As of December 31, 2011 only four of the FMC facilities had more than one isolation patient: BMA East Carolina, BMA Fayetteville, BMA Gastonia and BMA Lenoir. These four facilities all have more than 30 dialysis stations.
- In those cases where a single hepatitis B positive patient does dialyze, that patient essentially occupies the space of four patients. It is not appropriate to restrict access to care for three additional patients based upon the one patient with hepatitis B.
- It is more appropriate to allow facilities to develop the required isolation / separation capability without compromising the number of CON approved dialysis stations at the facility.
- Further, given the very low incidence of hepatitis B positive patients, it is not reasonable to expect a dialysis facility providing isolation for even three patients to meet the established performance rules of 3.2 patients per station. Of the four FMC facilities providing care to more than one isolation patient, only one of those facilities had three isolation patients.

Summary

For the forgoing reasons, Fresenius Medical Care does offer this petition to the State Health Coordinating Council. FMC believes that it is appropriate allow dialysis facilities to develop the isolation/separation capability without compromising the number of dialysis stations approved by the Certificate of Need. The number of patients requiring isolation/separation is less than 1%. FMC requests the SHCC to approve development isolation stations consistent with the recommendations of this petition: All facilities with less than 31 dialysis stations: 1 isolation station; all facilities with more than 30 dialysis stations: 2 isolation stations.