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
Utilization Standard

Submitted by:

Fresenius Medical Care
Jim Swann
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March 6, 2012

Petition to Amend ESRD Need Methodology

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Submitted at: DHSR/Medical Facilities Planning Section

Submitted to: Nadine Pfeiffer, Interim Branch Manager
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Long-Term and Behavioral Health Committee
N.C. State Health Coordinating Council

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- 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:

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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 the utilization standards for development of new dialysis stations and facilities should be increased to 95% versus the existing 80%. The North Carolina State Medical Facilities Plan, Chapter 14 includes the Basic Principles associated with methods for projection of new dialysis station need. Two of those Basic Principles are:

2. *New facilities must have a projected need for at least 10 stations (or 32 patients at 3.2 patients per station) to be cost effective and to assure quality of care.*

6. *No existing facility may expand unless its utilization is 80 percent or greater. Any facility at 80 percent utilization or greater may apply to expand.*

FMC proposes that the projected need determination should be increased such that CON applications to develop new facilities should be required to have a minimum of 12 stations and demonstrate 95% utilization, or 3.8 patients per station. Following is the recommended proposed language:

2. *New facilities must have a projected need for at least **12** stations (or **45.6** patients at **3.8** patients per station) to be cost effective and to assure quality of care.*

6. *No existing facility may expand unless its utilization is **95** percent or greater. Any facility at **95** percent utilization or greater may apply to expand.*

There are currently two need methodologies directly related to ESRD facilities: County Need Methodology and Facility Need Methodology. Both of these methodologies use an 80% utilization as the trigger for new/additional dialysis facilities and/or stations. FMC proposes that the existing need methodologies be changed to require a 95% utilization standard.

County Need Methodology:

County Need Methodology provides a projection of dialysis station need by using a five year average annual rate of change to project an ESRD patient population six months in the future. The methodology as it exists is completely functional and should be retained. FMC is proposing that the utilization threshold of 80% should be increased to 95% before a new facility is authorized.

Currently, the final step of the methodology involves an assessment of existing dialysis providers within the County. If the County has a deficit of 10 stations or more, and all dialysis facilities within the County are operating at or above 80%, then a County Need is determined. FMC proposes to raise the 80% threshold to at least 95%. The language would read as follows:

For the July SDR:

*If a county's December 31, XXXX projected station deficit is 12 or greater and the July SDR shows that utilization of each dialysis facility in the county is **95** percent or greater, the December 31, XXXX county station need determination is the same as the December 31, XXXX projected station deficit. If a county's December 31, 2011 projected station deficit is less than **12** or if the utilization of any dialysis facility in the county is less than **95** percent, the county's December 31, XXXX station need determination is zero.*

For the January SDR:

*If a county's June 30, (YEAR) projected station deficit is **12** or greater and the January SDR shows that utilization of each dialysis facility in the county is **95** percent or greater, the June 30, (YEAR) county station need determination is the same as the June 30, (YEAR) projected station deficit. If a county's June 30, (YEAR) projected station deficit is less than 12 or if the utilization of any dialysis facility in the county is less than **95** percent, the county's June 30, (YEAR) station need determination is zero.*

Facility Need Methodology:

FMC proposes similar and corresponding changes to the Facility Need Methodology. The methodology as it exists is completely functional and should be retained. FMC is proposing that the utilization threshold of 80% should be increased to 95% before additional dialysis stations are authorized. Proposed recommended language:

A. Its utilization, reported in the current SDR, is ***3.8*** patients per station or greater.

In addition, Step v. of the methodology should be changed as follows:

v. The sum from 3.B.iv is divided by ***3.8*** and from the quotient is subtracted the facility's current number of certified stations as recorded in the current SDR and the number of pending new stations for which a certificate of need has been issued. The remainder is the number of stations needed.

Reasons for the requested adjustment

Lower reimbursement from Medicare

- Medicare reimbursement for dialysis has been significantly reduced with implementation of the "bundled" reimbursement. As a consequence, FMC, and all dialysis providers are facing significant financial challenges as they attempt to remain profitable.
- This petition is NOT about profits. This is about financial sustainability. CMS is the predominant payor for ESRD services. CMS has cut reimbursement significantly with implementation of the bundle. FMC has always been cognizant of the need to control operational costs at dialysis facilities. The "bundle" has certainly made that all the more clear to providers across the country.
- Until implementation of the bundled reimbursement program by CMS, providers would bill for dialysis treatment and for ancillary services such as medications provided during treatment. With the advent of the bundled reimbursement, Medicare now reimburses providers a single rate for both treatment and ancillary services. That rate averages $234.00 per treatment in North Carolina. This is significantly below actual costs per treatment.
- Providers are able to remain financially viable by providing care and treatment to patients from other payor sources such as commercial insurance.
- At the present time, Medicare is the predominant payor for dialysis services. In 2011, approximately 85% of all patients at FMC facilities in N.C. were Medicare beneficiaries. FMC believes that this is common across the State and not specific to FMC facilities.
- As a consequence of low reimbursement from the predominant payor, facilities must struggle to remain financially viable.
- Increasing the utilization threshold to 95% will ensure that providers are more effectively utilizing existing and approved healthcare resources. Furthermore, this will also ensure that providers are not creating excess capacity to control markets.
- Providers should be encouraged to offer evening dialysis in order to maximize utilization.
    - Consider for example MRI equipment. An applicant for an MRI must demonstrate that the facility will operate a minimum of 66 hours per week.
    - There is no similar requirement for dialysis providers. Increasing the utilization threshold to 95% will encourage providers to capitalize upon existing and approved healthcare resources, in this case, dialysis stations.
    - In some urban markets, the SHCC could consider requiring a facility to operate a fifth dialysis shift.

- The addition of a 5th dialysis shift at a dialysis facility will not require additional capital expenditure on behalf of the facility.
- Consider the District of Columbia for example. Within the District, dialysis providers seeking additional stations or new facilities must demonstrate that the facility will be operating six dialysis shifts per week. Further, the facility must be operating at 85% capacity in order to be approved for additional stations. 85% capacity on six shifts is significantly higher utilization than required in North Carolina. A small 10 station facility would need to be dialyzing 51 patients in the District before applying for additional stations. That same facility in North Carolina would only require 32 patients in order to apply for additional stations. Clearly there is no intent to provide a wholesale comparison of North Carolina to the District of Columbia. The point here is that a requirement for higher utilization standards is not unreasonable and does provide for more effective utilization.

Alternative Considered: 5 Shift Methodology

- The existing Facility Need Methodology allows for development of new dialysis stations when a facility is operating at 80% capacity on four shifts. This four shift utilization standard leads to under-utilization of approved health care resources.
- Movement to a five shift standard would increase utilization at existing facilities by 25% without any capital outlay required of providers.
- It is not reasonable to enforce an expansion of operating hours for providers, especially in rural areas of North Carolina. An increase in the utilization standard does not force providers to expand operating hours, but certainly encourages increased hours.

High capital cost of development

- Development of a new dialysis facility is an expensive proposal. In the past several years, the CON Section has received many applications to develop new dialysis facilities. Even the small proposals are now projected to cost in excess of $1 million for development. Couple the development costs with the operational costs and the true costs is in the millions of dollars every year for a facility to remain financially healthy.
- Financial health is not about making huge profits for the corporation. It is aimed at keeping the facility open. Unfortunately, the provision of healthcare services—dialysis services, diagnostic services, nursing homes or hospitals or any other service regulated by the CON Section—all are in fact businesses. CON Review Criterion 5 clearly addresses the need for a health service facility to be profitable. Our legislators recognized this need and thus the CON Section is charged with reviewing CON applications with an eye to financial success.
- What happens if a facility fails financially? Ultimately it is the patient who is failed. In the case of dialysis patients, it is not as simple as saying, "well, ok,

we'll get an appointment for next week". Dialysis patients generally need treatment three times per week.

Capacity and Resources

- There is currently excess capacity; the number of new dialysis stations is increasing at a rate greater than the number of in-center patients
- FMC suggests that the SHCC should consider dialysis providers much the same as acute care hospital beds. As stated within the SMFP, Chapter 5, Acute Care Hospital Beds, Basic Principle A, Goal # 3 is "To protect the resource that the state's acute care hospitals represent." It is also appropriate for the SHCC to consider protection of the dialysis providers across the state. Certainly dialysis providers are essential health care services. In fact according to the January 2012 SDR, more than 14,000 citizens of North Carolina are dependent upon dialysis treatment.
- An adequate number of dialysis facilities currently exists in most North Carolina Counties. Only Macon County has a Need Determination in the January 2012 SDR. That Need Determination is an adjusted need arising from a petition by the County.
- Of 100 North Carolina Counties, according to the January 2012 SDR, only 34 counties have a deficit of dialysis stations. Of these 34, four counties are within the two multi-county dialysis planning areas (Cherokee-Clay-Graham or Avery-Mitchell-Yancey). Of the remaining Counties, 10 have very small ESRD patient populations and do not qualify for even a 10 station facility. Absent petitions for adjusted need determinations, (as in Macon County, 2011 for the 2012 SMFP) it is likely to be several years before these Counties will have a patient population large enough to warrant development of a dialysis facility.
- The January 2012 SDR notes that lass than half of the current facilities (72 of 174) were at or above the 80% utilization threshold.
- The January 2012 SDR reports that there are 175 ESRD facilities certified and operating in North Carolina. These 175 facilities included 4,160 dialysis stations. The SDR reports another 308 dialysis stations at some stage of development or CON review.
- Compare this to the January 2007 SDR. That SDR reports that there were 147 ESRD facilities certified and operating in North Carolina. These 147 facilities included 3,550 dialysis stations. The SDR reported another 348 dialysis stations at some stage of development or CON review.
- Thus, the number of facilities has increased by 19%. At the same time the number of certified dialysis stations has increased by 612 stations or 17.2%.
- During this same time, the number of dialysis patients has increased from 12,260 (January 2007 SDR, Table B) to 14,455 (January 2012 SDR, Table B) (both tables reporting ESRD Census for June 30 of respective years). This is an increase of 2,195 patients, or 17.91%. However, and of significant importance, the number of home patients increased from 1,077 or 9% of the ESRD patient population in 2007 to 1,605, or 11.11% of the ESRD patient population in 2011. For the five years ended June 30, 2011, the ESRD home

patient population has increased by 49%, while the ESRD patient population as a whole has increased by only 17.9%. The number of patients choosing home dialysis over in-center dialysis is certainly increasing. As the home patient population growth outpaces the ESRD patient population as a whole, the need for new/additional in-center dialysis stations decreases.

- The home hemo-dialysis population is increasing dramatically. According to the Southeastern Kidney Council zip code report for the period ended December 31, 2006, there were 31 patients in our State using home hemo-dialysis. However, SEKC reports that at the end of September 2011, there were 258 home hemo-dialysis patients in our State. Based upon FMC experience within North Carolina and nationwide, this trend is expected to continue.

Exceptions to the requested adjustment

FMC clearly recognizes the burden of travel to and from dialysis rests upon the patient. FMC suggests that the current 80% standard be continued for any County (or future multi-county combined service area) without a dialysis facility. Continuance of the current standard in these few situations will result in CON approval of a dialysis facility in these Counties sooner rather than later.

Summary

For the forgoing reasons, Fresenius Medical Care does offer this petition to the State Health Coordinating Council. FMC believes that it is appropriate to increase the utilization standard requirement to 95% for development of new facilities and for expansion of existing facilities as stated herein. Further, FMC suggests that any new dialysis facility should be required to have a minimum of 12 stations (except as discussed within the above noted exception). FMC does note the exception to this rule should be those counties which currently do not enjoy the benefit of a dialysis facility within the county.