Long-Term & Behavioral Health Committee

Agency Report for Petition to
Amend ESRD Need Methodology to
Exclude Isolation/Separation Stations

Proposed 2013 State Medical Facilities Plan

Petitioner:

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

Request:

The Petition requests isolation/separation stations be excluded from the dialysis station methodology, allowing existing and approved dialysis facilities to develop isolation/separation stations outside of the scope of Certificate of Need (CON). The petitioner also requests a database be complied of all existing and approved dialysis providers to determine the number of isolation stations currently available in North Carolina.

Background Information:

The current dialysis methodology was established in 1993. It assesses individual "County Need" for each of North Carolina's 100 counties on a semiannual basis. At this time, all hemodialysis stations used for chronic outpatient dialysis patients who report data to the Centers for Medicare and Medicaid (CMS) through the Southeastern Kidney Council are counted in the methodology.

On April 15, 2008, CMS issued the End Stage Renal Disease (ESRD) Conditions Final Rule updating CMS's standard for delivering safe, high-quality care to dialysis patients. Provisions of the rule were effective on October 14, 2008, which required dialysis providers with existing facilities that began caring for Hepatitis B positive (HBV+) patients after February 9, 2009 to designate an isolation area or obtain a waiver of the requirement. According to CMS, "…an isolation "area" is separated from other stations by a space at least equivalent to that of another dialysis station." There is no requirement by CMS for an existing facility to build an isolation room. However, if an existing facility expands their treatment area, they are expected to add an isolation station or obtain a waiver. If the existing facility only adds stations without expanding the treatment area, they would not have to add an isolation area or obtain a waiver.

If there are multiple HBV+ patients receiving treatment, CMS says, they can use the same area, machine and chair, with routine cleaning and disinfecting. However, an isolation area cannot be used for non-HBV+ patients in between uses for HBV+ patients' treatments. CMS does not require a facility to obtain a waiver to use an isolation area after all HBV+ positive patients have been discharged and the area has been cleaned and disinfected. Dialysis facilities are not prevented from using isolation areas for non-HBV+ patients when they no longer have HBV+ patients in their caseload.

Analysis of Petition:
As reported in the January 2012 Semiannual Dialysis Report, in June 30, 2011 there were 4,111 certified dialysis stations (*for chronic outpatient dialysis*) serving a total of 12,774 patients. At capacity, 4 patients per station, as currently defined in the methodology this would equal 77.7 percent utilization of the existing capacity. By December 23, 2011 there were 175 End-Stage Renal Disease (ESRD) dialysis facilities certified and operating in North Carolina, providing 4,160 dialysis stations, with an additional 217 dialysis stations that are CON-approved but not certified.

The petition seeks to allow additional stations at the rate of “1 isolation station” for each facility with 30 or fewer stations and “2 isolation stations” for each facility with more than 30 stations. As of December 23, 2011 there were 132 facilities meeting the first criteria; with an additional 43 facilities having more than 30 stations. Applying this requested change to the data from December 23, 2011 would have authorized an additional 218 hemodialysis stations for “isolation” purposes.

The petition indicates that the national “…prevalence of hepatitis B…positivity among U.S. dialysis patients was approximately 1%,” while the experience at Fresenius facilities was “…less than 0.5% of the patients served by FMC”. Applying these percentages to the total residents of North Carolina receiving dialysis as reported for June 30, 2011 through the Southeastern Kidney Council (*i.e., 14,455 dialysis patients*), the anticipated number of Hepatitis B positive dialysis patients residing in North Carolina would be between 72 and 145. Further, since Fresenius operates 85 or the 175 dialysis facilities currently in operation in North Carolina (*i.e., 49% of the facilities*) but only reports a total of 27 patients that were Hepatitis B positive, the actual number may be significantly lower (*i.e., in the range of 55 to 56 patients*).

The Petitioner has not provided sufficient data to document that HVB+ patient needs cannot be addressed by existing dialysis station capacity or that there is a need for 218 additional hemodialysis stations to address the perceived need.

It is also important to note, as indicated in the comments from DaVita, that all additions of hemodialysis stations are subject to Certificate of Need review.

Agency Recommendation:
Given the low number of anticipated Hepatitis B positive patients and given the fact that the standard methodology allows existing facilities to expand if their utilization is at or above 80% (which allows for flexible capacity), the Agency recommends that the petition be denied. If any facility is experiencing difficulty serving the general needs of dialysis patients because that facility is following requirements to meet the needs of one or more patients who are Hepatitis B positive, the facility may consider requesting an adjusted need determination based on its unique circumstances. This issue could be addressed on a case-by-case basis, not by a general exception to the methodology.