



September 30, 2013

Delivered Via E-mail: [fslcon@doh.wa.gov](mailto:fslcon@doh.wa.gov)

RE: Kidney Dialysis Rules

Fresenius Medical Care North America appreciates the opportunity to submit comments in anticipation of the upcoming stakeholder meetings regarding the Certificate of Need process for Washington dialysis providers.

Our comments are as follows:

**246-310-280—Definitions**

In this section, Fresenius Medical Care (FMC) recommends the following:

- 1) Confirm that the zip codes for each of the planning areas are up to date, and establish a process for ongoing updates.
- 2) We suggest a definition of “active station.” Until relatively recently, dialysis facilities could secure CN approval and build out more stations than they were authorized to operate. While facilities were limited in how many stations could be used at any one time to the number of stations that were authorized, in the past, this flexibility allowed the facility to serve more patients during regular working hours because it didn’t need to build in down time to clean the stations...it could simply use another station. The loss of this flexibility, coupled with #3 and #4 below has served to seriously restrict access.
- 3) Facilities are required under CMS rules to have an isolation station. Typically, well less than 5% of dialyses are performed on an isolation station. Yet, in Washington, the isolation station must count against a facility’s total stations, even though it can only be used for isolation. CMS does not place does not a similar restriction on the station. Rather, CMS requires that if a facility has an isolation patient on the census that the room can only be used for the isolation patients. However, the station can be used for regular patients if no Hepatitis positive patients are on the census. Under the CN Program’s current interpretation, an isolation station could be sitting vacant and in-center patients might be forced onto a 4<sup>th</sup> shift due to occupancy. Because the CN Program restricts the use of the isolation station, FMC requests that the isolation station be



## FRESENIUS MEDICAL CARE

a “+1” to the station count, meaning that it would be in addition to the number of stations needed per the methodology and would be added to the number of stations approved for in-center use. In that way, it wouldn’t limit patient access.

- 4) Similarly to the issue raised in 3) above, facilities often designate a station for use for home training. This station is currently counted in the total number of stations, but again, the CN Program recently eliminated the ability to use this station for in-center dialysis when not being used for training. We request that facilities be allowed to designate up to three stations that would be used exclusively for training, and that these stations be in addition to those authorized and identified as needed per the methodology. We believe the addition of these stations to be consistent with the requests of both health care purchasers (Health Care Authority) and the needs of consumers and assure access.

Several of the changes suggested concerning flexibility on the use of dialysis stations, and the add-ons for isolation as well as home training, may require an additional WAC, or changes to WAC 246-310-287, Exceptions.

### **246-310-282—Concurrent Review Cycle**

- (1) We recommend reducing the concurrent review cycle to two times a year.
- (2) We believe the review cycle needs to be aligned with the release of NWRN data. At the current time, it is not. We know it is the CN Program’s goal to issue timely decisions. We know that this has not been occurring. We welcome a discussion with the CN Program concerning any suggestions for modification to the rules that would allow for more timely decisions.
- (3) Because decisions are not timely, providers submitting applications can be in the situation wherein another application is under review at the time they submit their new application. We suggest that if a provider submits an application for stations, and those stations are ultimately awarded to the first applicant, prior to the decision date on the new application, that the provider’s application fee be totally refunded.



**246-310-284-Methodology**

We recommend that applicants not be allowed to submit multiple applications in the same planning area during a given concurrent review cycle that, in total, request more stations than are identified as needed in the planning area. While not anticipated when the rules were modified in 2007, some providers submit multiple applications wanting to assure a point in the tiebreaker contest for the best location. This has caused undue expense for the competing applications and for the CN Program.

In addition, consistent with the recent Clark County settlement we suggest language which says that if certain occupancy levels are not achieved within four years of opening, that only the number of stations needed to operate at 80% be retained, and the other stations be revoked.

**WAC 246-310-286 Standards for planning areas without an existing facility**

This section needs to be updated as many of the planning areas listed now have facilities.

**246-310-287- Exceptions**

The goal of this section was to operate as a “safety valve” in the event that the remaining CN rules did not accurately reflect patient demand in a specific geography or for a specific provider. However, this standard has failed because of the requirements within this WAC that tie the CN Program’s hands. Subsection (1) states that: “All other applicable review criteria and standards have been met.” If a provider is operating at even 150%+ of capacity, it cannot request new stations under this standard if any other standard is not met. Patient access has been adversely impacted by the failure of this standard.

FMC is suggesting a major reworking of this WAC based on our experience in Clark and Benton Counties, in particular. On behalf of patients needing dialysis services, we should not allow these situations to be repeated. We all need to learn from what happened in Clark County, and we welcome a discussion with the CN Program and other providers. Our focus needs to be consumer access to dialysis services. We suggest the following:

- a) New language that allows an existing provider to expand:
  - a. If it has reached and sustained a certain occupancy level and if all other facilities owned by the applicant in the same planning area are operating at or above 80% even if other providers in the planning area have not attained 80% occupancy.



## FRESENIUS MEDICAL CARE

- i. If there are new stations needed in a planning area, the provider above the selected occupancy should be able to submit a CN requesting all of these stations. The provider can submit a CN as soon as NWRN data demonstrates that:
    1. It has operated at 90% or greater occupancy for 8 consecutive quarters (2 years)
    2. It has operated at 100% occupancy for 4 quarters (1 year)
    3. It has operated at 110% occupancy for 2 quarters (6 months)
  - ii. If there are no new stations needed, the provider should be able to submit a CN requesting sufficient stations to bring its utilization to 80%.
- b. If there is station need and a provider has achieved 80% occupancy, the provider should be allowed to submit a CN even if there is a CN approved provider in the same planning area if more than 24 months have elapsed since that CN approved provider's CN was issued, but they have not yet certified and opened their facility for patient care.
- b) The language in this section requiring "All other applicable review criteria and standards have been met" should be eliminated.

### **246-310-288 - Tiebreakers**

FMC recommends changes to this section because the tiebreaker is not functioning as intended. We think we need both additional tiebreaker criteria, and as well as an understanding that a tiebreaker section does not replace the need for the CN Program to do its analysis of superior alternatives under cost containment prior to tiebreakers.

- a. We need to add language to assure that in cost containment, the analysis of "best available alternative" include factors such as history of achieving utilization projections at other facilities operated by the applicant in Washington both within the planning area and in other planning areas. (This would be determined by calculating the variance of actual occupancy to that projected in the CN application associated with the facility).



**FRESENIUS  
MEDICAL CARE**

- b. Allow a tiebreaker point to be awarded if home training is offered by the applicant within 35 miles of the proposed facility (regardless of whether the other dialysis facility is in or outside of the planning area). This would allow for efficient use of existing resources, where dialysis facilities are located reasonably close one another.
- c. Requirement that a permanent bed be an actual bed, not a reclining chair.

**A. 246-310-289- Relocation**

FMC does not recommend any changes to this section.

Thank you for the opportunity to submit comments.

Sincerely,

Jeff Eustis  
Director of Operations  
Fresenius Medical Care  
Phone: 503.477.0076  
Email: [jeff.eustis@fmc-na.com](mailto:jeff.eustis@fmc-na.com)

Ann Sullivan  
Director of Operations  
Fresenius Medical Care  
Phone: 509.222.8011  
Email: [ann.sullivan@fmc-na.com](mailto:ann.sullivan@fmc-na.com)

Mitch Long  
Director of Operations  
Fresenius Medical Care  
Phone: 509.710.6705  
Email: [mitch.long@fmc-na.com](mailto:mitch.long@fmc-na.com)