



Memorandum

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From: Stan Bower, Director of Operations


Date: December 13, 2013

Subject: Comments in preparation for meeting on December 19th

In preparation for the upcoming Certificate of Need work session on December 19th, the following comments are submitted on behalf of Fresenius Medical Care (Fresenius).

Isolation stations:

At the November meeting, we had a robust discussion about isolation stations. We believe the consensus was that there should be a +1 for an isolation station, and that the +1:

- should not be counted in the methodology for the total number of stations; and
- may only be used for isolation. This means no swing status

We affirm those decisions.

Isolation Station Grandfathering:

At the present time, isolation stations are within the methodology, and have a swing status. If an isolation station is in use, it counts as an “active station.” Fresenius suggests that DOH create some process or rule language (a grandfather provision) that allows a +1 for isolation stations of existing dialysis facilities so that the rules are consistent for all providers.

Training areas/spaces for Home Hemo and Home PD:

At the November meeting there was a general consensus that home training should be outside the CN methodology because it is most often done in a different space with different machines (or no machines for some types of PD), etc. However, we do not recall any consensus beyond what we’ve noted. Fresenius had proposed limits on the number of training areas/spaces, while others wanted no limits.

Fresenius continues to support the proposal we submitted prior to the November meeting, with a change to allow for additional training areas. We believe it strikes the right balance. It provides flexibility for dialysis providers while adhering to Certificate of Need principles by establishing a set number of areas/spaces for training. And, in addition, it will improve patient access for home hemo and home PD training.

As a review, here is our proposal. Our change is noted:

- In order to increase access for home therapy training, home therapies should not be counted in the CN methodology, but rather treated separately, subject to the following.
 - Training areas must be within an in-center dialysis facility by either being located within the dialysis facility or another in-center facility owned by the same company in the same or nearby planning area.
 - The maximum number of home therapy training areas is ~~(20%)~~ 30% of the total number of in-center stations, but in no case less than 2. Any number over ½ is rounded up to the next number.
 - Home therapy training areas must be used exclusively for training.

Home Training Area/Spaces Grandfathering:

At the present time, dialysis training areas/spaces are considered within the Certificate of Need methodology. If a facility is doing home training in its in-center program, it counts as an “active” station. Fresenius suggests that DOH creates some process or rule language that allows training areas/spaces of existing dialysis facilities to be “grandfathered” so that the rules are consistent for all providers.

Tri-State Memorial Hospital (TSMH):

Fresenius opposes the changes suggested by Tri-State Memorial Hospital (TSMH). Fresenius believes that the challenges faced by TSMH are essentially an operations issue, not a certificate of need issue.

Maintaining a level playing field for all dialysis facilities operating in Washington State is crucial to the integrity of the certificate of need process. We do not believe this proposal is consistent with this principle in its current form. In essence, it would give one provider a “lock” on this planning area for the foreseeable future.

To reiterate Fresenius opposes the changes suggested and would oppose an expedited rule process.

Station utilization. We have been asked to comment on how to create a “release valve” for facilities that are at or over capacity. One option presented is to reduce the number for station usage in non-rural counties from 4.8 to 3.2.

Fresenius believes a change from 4.8 to 3.2 is too large and will create situations not consistent with certificate of need principles by creating an additional 30-50% capacity in excess of the current need standard.

A reduction from 4.8 to 3.2 would create a “gold rush.” This “gold rush” would be administratively challenging for the Department of Health, as the Department is not sufficiently staffed to process the multitude of new CN applications that such a change would produce.

We think a better approach is 4.0, the midpoint between 4.8 and 3.2. Lowering the number to 4.0 provides a much needed “safety valve” in a complex system while adhering to the basic principles of certificate of need.

The following are some examples of the differences between using 4.8, 4.0, and 3.2.

Clark County:

- Projected need in 2016 at 4.8 is 98 stations (includes DaVita’s 12 Battleground stations)
- Projected need in 2016 at 4.0 is 118 stations
- Projected need in 2016 at 3.2 is 147 stations

King 1:

- Projected need in 2016 at 4.8 is 40 stations
- Projected need in 2016 at 4.0 is 47 stations
- Projected need in 2016 at 3.2 is 59 stations

Lewis County:

- Projected need in 2016 at 4.8 is 14 stations
- Projected need in 2016 at 4.0 is 17 stations
- Projected need in 2016 at 3.2 is 21 stations

While our goal is to write rules that lower the rate of litigation, and decrease the time from filing a certificate of need to bringing those needed stations on-line, we must also realize that no set of rules will be perfect and that delays of various types will occur. As our contribution to the broader “release valve” discussion, we are inserting our earlier comments submitted on September 30, 2013 on the topic of exceptions. Please see below.

“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 even if other providers in the planning area have not attained 80% occupancy.
 - 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."