FRESENIUS MEDICAL CARE

November 13, 2023

Ross Valore, Executive Director
Eric Hernandez, Manager
Certificate of Need Program
CNrulemaking@doh.wa.gov

RE: WSR 23-16-038, CR-101 for ESRD Rules to Implement SSB 5569

Dear Mr. Valore and Mr. Hernandez,

Fresenius Medical Care North America ("FMCNA") appreciates the opportunity to provide comments on the proposed rulemaking pursuant to the CR-101 filed on July 24, 2023 to implement Substitute Senate Bill 5569 related to kidney dialysis facilities. FMCNA also appreciates the Department publishing its recent draft set of proposed rule changes sent on November 1st when notifying stakeholders of the upcoming public rules workshops to be held on November 28th.

Please find attached FMCNA's written comments and proposed rule changes for the Department's consideration in drafting rules to implement SSB 5569.

If you have any questions or need additional information, please do not hesitate to contact me at maria.c.garcia@freseniusmedicalcare.com or 707.246.2773.

Sincerely,

Maria Garcia
Senior Director, State Government Affairs
Fresenius Medical Care North America

Fresenius Medical Care North America
Written comments for rulemaking under [CR-101] WSR 23-16-038
November 2023

TABLE OF CONTENTS

TABLE OF TABLES

WAC 246-310-812 Kidney disease treatment facilities—Methodology.

FMCNA supports the Department's proposed rule changes in WAC 246-310-812(4), (5)(a), (5)(c), (6)(a), and (6)(c) presented in the DRAFT ESRD Rule Language.pdf file distributed on November 1st.

To help provide additional clarity with respect to WAC 246-310-812(5)(c) and (6)(c), FMCNA has developed a set of hypothetical scenarios. Presented below as Scenario #1 is a hypothetical scenario of a planning area with three kidney dialysis facilities (Facilities A – C) where Facility B is impacted by a natural disaster and must temporarily close its seven (7) stations. Facility A is granted its request to operate seven (7) additional temporary emergency stations to serve Facility B's patients for the interim period.

Table 1: Nonspecial Circumstance Scenario #1

	Facility A	Facility B	Facility C
CN Permanent Stations	17	7	10
# of Patients (assuming no temporary emergency)	80	36	50
Patient Per Station Occupancy (Assuming no temp emergency)	4.71	5.14	5.00
Affected by Temporary Emergency?	Yes (Stations Added)	Yes (Temp Closure)	No
Temporary Stations	7	0	0
Temporary # of Patients	36	-36	0
Total Patients (what would appear in hypothetical modality report)	116	0	50
Occupancy Based on Total Patients Divided by Permanent Stations	6.82	0.00	5.00
Clear Department's review of WAC 246-310-812(5)?	Yes (Affected Facility)	Yes (Affected Facility)	Yes (Above 4.5 Standard)

Under existing rules with none of the proposed rule changes implemented, the Department would be unable to approve new nonspecial stations in the planning area, as Facility B's patient occupancy would be 0.00 patients per station (i.e. below the 4.5 patient per station occupancy standard established in existing WAC 246-310-812(5)).

Under proposed rule change WAC 246-310-812(5)(c), Facility A and Facility B would both 'clear' the Department's nonspecial need calculations as they are both deemed affected facilities. Importantly, although in Scenario #1 both Facility A and Facility B are assumed to have patient occupancies above the 4.5 standard under normal circumstances (i.e. no temporary emergency), the reason why they are 'cleared' is NOT dependent on this hypothetical occupancy under normal circumstances. This is because the counterfactual occupancy under normal circumstances is unavailable in the modality report---only the actual total patient count is available in the modality report. This limitation in available information is further described in Scenario #2.

Scenario #2 presented below uses the same three planning area providers, but Facility A now has a hypothetical patient occupancy under normal circumstances below the 4.5 occupancy standard. In this scenario, Facility A is still 'cleared' through because it is an affected facility despite having a hypothetical patient occupancy below the 4.5 occupancy standard. While we have the benefit of assuming a typical occupancy rate under normal circumstances in this hypothetical Scenario #2, only the actual patient census reported in the modality report will be available during the implementation of these rules. See Table 3 below for an example of the data in Scenario #2 that will be available to a prospective applicant and the Department at the time of its evaluation.

Table 2: Nonspecial Circumstance Scenario #2

	Facility A	Facility B	Facility C
CN Permanent Stations	17	7	10
# of Patients (assuming no temporary emergency)	60	36	50
Patient Per Station Occupancy (Assuming no temp emergency)	3.53	5.14	5.00
Affected by Temporary Emergency?	Yes (Stations Added)	Yes (Temp Closure)	No
Temporary Stations	7	0	0
Temporary # of Patients	36	-36	0
Total Patients (what would appear in hypothetical modality report)	96	0	50
Occupancy Based on Total Patients Divided by Permanent Stations	5.65	0.00	5.00
Clear Department's review of WAC 246-310-812(5)?	Yes (Affected Facility)	Yes (Affected Facility)	Yes (Above 4.5 Standard)

Table 3: Nonspecial Circumstance Scenario #2 (Only total patients shown)

	Facility A	Facility B	Facility C
CN Permanent Stations	17	7	10
Affected by Temporary Emergency?	Yes (Stations Added)	Yes (Temp Closure)	No
Temporary Stations	7	0	0
Total Patients (what would appear in hypothetical modality report)	96	0	50
Occupancy Based on Total Patients Divided by Permanent Stations	5.65	0.00	5.00
Clear Department's review of WAC 246-310-812(5)?	Yes (Affected Facility)	Yes (Affected Facility)	Yes (Above 4.5 Standard)

Up to this point, Scenarios #1-2 have focused on a non-staffing shortage emergency temporary emergency. The new proposed rule WAC 246-310-812(5)(c), as currently written, would also 'clear' any facility affected by a staffing shortage, regardless of the facility's patient per station occupancy rate. Scenario #3 below presents a scenario where one facility (Facility X) is affected by a staffing shortage temporary emergency. Facility X has received approval to operate seven (7) additional temporary stations to expand capacity during its day shifts due to temporary limitation in being able to staff its evening shift.

Table 4: Nonspecial Circumstance Scenario #3

	Facility A	Facility B	Facility C
CN Permanent Stations	17	7	10
# of Patients (Assuming no temporary emergency)	60	36	50
Patient Per Station Occupancy (Assuming no temporary emergency)	3.53	5.14	5.00
Affected by Temporary Emergency?	Yes (Staffing Shortage)	No	No
Temporary Stations	7	0	0
Temporary # of Patients	0	0	0
Total Patients (what would appear in hypothetical modality report)	60	36	50
Occupancy Based on Total Patients Divided by Permanent Stations	3.53	5.14	5.00
Clear Department's review of WAC 246-310-812(5)?	Yes (Affected Facility)	Yes (Above 4.5 Standard)	Yes (Above 4.5 Standard)

While there are opportunities to carveout staffing shortages from the nonspecial need calculations in WAC 246-310-812(5)(c) and (6)(c) because staffing shortages will have less of an effect on the patient occupancy, FMCNA recommends keeping this subsection general to all temporary emergencies. Incorporating a staffing shortage carveout to the nonspecial need calculations introduces the opportunity for uncertainty and disagreement by prospective applicants during a concurrent review process that could lead to costly litigation. For example, what if a facility approved for a staffing shortage temporary emergency has a patient occupancy reported in the ESRD Network 16 data that exceeds the number of patients at the time of its request (i.e. exceeds maximum allowed under RCW 70.38.280(2)(d))? While there could be additional calculation modifications added to WAC 246-310-812(5)(c) and (6)(c) to restrict patient census for staffing shortages to the maximum allowed under RCW 70.38.280(2)(d), this would add an additional layer of complexity to the nonspecial review process. It would also require timely publication of temporary exemption request and determination documents to the Department's website to ensure that all market participants have access to the same information when reviewing which planning areas are open to new applications in the upcoming review cycle.

As will be discussed in the following section, a carveout for staffing shortages is appropriate and manageable for special circumstances requesting +1/+2 stations. This is because a special circumstance application is a well contained application and review process specific to the applicant.

WAC 246-310-818 Special circumstances one- or two-station expansion—Eligibility criteria and application process.

FMCNA supports the Department's current proposed language for WAC 246-310-818(14), but it also advocates new sections (14)(b) and (c) be added:

> (14) The department will review special circumstance requests with the following considerations related to temporary emergency stations defined in WAC 246-310-825:
> (a) All calculations described in this section exclude temporary emergency stations.
> (b) A facility that operated temporary emergency stations during the most recent six consecutive month period preceding the letter of intent submission date is ineligible for applying for special circumstances unless the temporary emergency stations were approved to address a staffing shortage emergency situation identified in RCW 70.38.280(2)(d).
> (c) Pursuant to RCW 70.38.280(2)(d), a facility that operated temporary emergency stations due to a staffing shortage emergency situation may not exceed the number of patients served at the time of the emergency request. All calculations described in this section for the review of a facility that operated temporary emergency stations due to staffing shortage emergency will have its patient census reported in the ESRD Network 16 data set to a maximum of the patients served at the time of the emergency request for the months when the temporary emergency was in effect.

Presented below are two special circumstance scenarios to highlight the difference in how a facility's patient occupancy would be affected by a staffing shortage temporary emergency (Special Scenario #1) and a natural disaster temporary emergency (Special Scenario #2).

Table 5: Special Circumstance Scenario #1

	6 Months Prior to Letter of Intent					
	Not Temporary Emergency			Temporary Emergency (Staffing Shortage)*		Not Temporary Emergency
	Oct 2023	Nov 2023	Dec 2023	Jan 2024	Feb 2024	Mar 2024
Patients	112	107	110	110	110	112
Permanent Stations	20	20	20	20	20	20
Occupancy	5.6	5.35	5.5	5.5	5.5	5.6

*This scenario assumes the facility in question (Facility) was granted temporary emergency stations to address a staffing shortage emergency.

Table 6: Special Circumstance Scenario #2

	6 Months Prior to Letter of Intent					
	Not Temporary Emergency			Temporary Emergency*		Not Temporary Emergency
	Oct 2023	Nov 2023	Dec 2023	Jan 2024	Feb 2024	Mar 2024
Patients	93	88	90	125	125	92
Permanent Stations	20	20	20	20	20	20
Occupancy	4.65	4.4	4.5	6.25	6.25	4.6

*This scenario assumes the facility in question (Facility A) was granted temporary emergency stations to absorb patients from Facility B that was severely affected by a natural disaster.

As demonstrated by Special Scenario #2, a facility's patient census and patient-per-station occupancy can be distorted if it is operating additional temporary emergency stations during a non-staffing shortage emergency. However, Special Scenario #1 shows that this issue is mitigated for staffing shortage emergencies, as RCW 70.38.280(2)(d) institutes a maximum patient threshold on facilities requesting temporary stations for staffing reasons. Therefore, the facility's patient census and patient-per-station occupancy estimates will not be artificially high.

New section WAC 246-310-818(14)(c) adds language to modify calculations in the event a facility has patient census data reported in the ESRD Network 16 data that exceeds its maximum number of patients allowed under RCW 70.38.280(2)(d).

Overall, facilities operating temporary emergency stations due to staffing shortages should be allowed to apply for special circumstance given the patient census maximum instituted under RCW 70.38.280(2)(d). This can be implemented through the adoption of the proposed new sections WAC 246-310-818(14)(b) and (c).

WAC 246-310-825 Kidney disease treatment facilities – Temporary emergency situation exemption.

FMCNA is supportive of the proposed rule changes in new section WAC 246-310-825, as presented in the DRAFT ESRD Rule Language.pdf file distributed on November 1st. FMCNA presents the following minor comments regarding new section WAC 246-310-825.

a. *Revise title to include 'centers' in place of 'facilities'*

FMCNA recognizes that the existing rules use "kidney disease treatment centers" and "kidney disease treatment facilities" interchangeably in the section titles. In the interest of being consistent with the terminology of "kidney disease treatment *center*" and "kidney dialysis *facility*" defined in WAC 246-310-800(10), FMCNA recommends that the section title for the new standalone temporary emergency station be modified to use "centers" in place of "facilities".

b. *Comments on list of affected facilities in WAC 246-310-825(3)(b: "For temporary emergency situations other than those caused by staffing shortages, identify each facility expected to be affected by the temporary emergency situation."*

FMCNA agrees with the Department that a list of affected facilities is unnecessary for a staffing shortage temporary emergency, as staffing shortage temporary emergencies necessarily only affect the one facility requesting the temporary stations (i.e. the list of affected facilities in staffing shortages is only the facility requesting the exemption).

FMCNA wishes to further clarify what should be considered a valid list of affected facilities that will (1) be published on the Department's website pursuant to proposed WAC 246-310-825(7) and (2) incorporated into the Department's nonspecial need methodology in proposed WAC 246-310-825(5)(c) and (6)(c).

A valid list of affected facilities should only include:

1. The facility requesting temporary emergency stations; and
2. A facility that is required to suspend operations, in part or in its entirety, due to circumstances that qualify as a temporary emergency situation.

Note: for staffing shortage emergencies, only the facility requesting temporary emergency stations (#1) is valid.

Returning to Nonspecial Scenario #1, Facility A and Facility B would both be deemed an affected facility, as Facility B would be the facility impacted by a temporary emergency and forced to temporarily suspend operations, while Facility A would be the facility requesting additional stations to be able to care for Facility B's patients on an interim basis.

The rules as currently written require the applicant to provide this list. The Department should be able to correct this list in its determination letter if the applicant includes an invalid facility. For example, if Facility A in Nonspecial Scenario #1 also included Facility C in its list of affected facilities, then the Department should be able to correct the list of affected facilities to only include Facility A and Facility B.

General Comments

a. *References to Northwest Renal Network / Comagine Network*

The Department's Workbook_for_November_28_Rule_Workshop.pdf file distributed on November 1st identifies a potential action item as "Should all references to "Northwest Renal Network" be amended to state "Comagine?" FMCNA recommends if a change in the references is made, then all references should be amended to simply "ESRD Network 16".

b. *References to WAC 246-310-825 and RCW70.38.280*

FMCNA recommends references of the new temporary emergency exemption rules include references to both WAC 246-310-825 and RCW 70.38.280. The following sections have references that should be updated:

- WAC 246-310-812(4)(d)
- WAC 246-310-812(5)(a)
- WAC 246-310-812(5)(c)
- WAC 246-310-812(6)(a)
- WAC 246-310-812(6)(c)
- WAC 246-310-818(14)

c. *References to 'Centers' and 'Facilities'*

FMCNA recommends that the rules use either "kidney disease treatment center" or "kidney dialysis facility", consistent with the definitions presented in the existing WAC 246-310-800(10). Any reference to "kidney disease treatment facilities' ought to be corrected to "kidney disease treatment centers".