



FRESENIUS MEDICAL CARE

August 23, 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. We are supportive and appreciative that the Department of Health’s Certificate of Need Program issued this CR-101 and is seeking stakeholder input early in the process.

Please find attached FMCNA’s written comments and recommendations 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

On April 6, 2023, Washington Governor Jay Inslee signed Substitute Senate Bill 5569 (SSB 5569). It became effective on July 23, 2023. SSB 5569 added a new section to Chapter 70.38 RCW to create exemptions from certificate of need requirements for kidney dialysis facilities during temporary emergency situations upon approval by the Department of Health. Specifically, the law allows kidney dialysis facilities to exceed the number of dialysis stations authorized by their certificate of need during temporary emergency situations that create an urgent need for additional dialysis capacity.

On July 24, 2023, the Washington State Department of Health (“Department”) filed a CR-101 to initiate rulemaking to implement SSB 5569. The Department’s statement indicates it is considering creating new rules defining "temporary emergency situation" and establishing processes for kidney dialysis facilities to apply for exemptions under the new law, as well as amending existing kidney dialysis facility rules, WAC 246-310-800 through WAC 246-310-833, based on the effects of creating a new exemption for kidney dialysis facilities pursuant to SSB 5569.

Additionally, in an email dated July 28, 2023, the Department stated it will be holding upcoming listening sessions and workshops to gather input on rulemaking to implement SSB 5569. As an organization operating multiple dialysis facilities in Washington, Fresenius Medical Care North America (“FMCNA”) appreciates the Department seeking early input from stakeholders on ESRD rulemaking.

A summary of FMCNA’s recommendations for the Department’s consideration in drafting rules to implement SSB 5569 is presented below and further described in this comment letter:

1. Define “temporary emergency situation” in the Washington Administrative Code to include additions for disease outbreaks, severe disruption to transportation infrastructure, and state and federal emergency declarations that have a direct impact on patient access to kidney dialysis services.
2. Define which facilities are considered to be an ‘affected facility’ when a temporary emergency station exemption is invoked.
3. Exclude temporary emergency stations from need calculations in WAC 246-310-812.
4. Assure that station use rates at affected facilities invoking the temporary emergency exemption are not a barrier to additional new stations needed under WAC 246-310-812.
5. Exclude facilities affected by non-staffing shortage emergencies from special circumstance expansions in WAC 246-310-818. However, this exemption should not apply to facilities approved for temporary emergency stations for staffing shortage emergencies; such facilities should be allowed to apply for additional stations under WAC 246-310-818, where the additional, temporary stations are not counted.
6. Adopt rules to assure that requests for temporary emergency exemptions may be filed at any time.

7. Adopt rules to clarify that a temporary closure of operations at a facility due to an event that qualifies as a temporary emergency situation does not extinguish that facility's certificate of need.
8. Add temporary emergency exemptions data reporting requirements to WAC 246-310-803.

Recommendation 1. Define “temporary emergency situation” in the Washington Administrative Code to include additions for disease outbreaks, severe disruption to transportation infrastructure, and state and federal emergency declarations that have a direct impact on patient access to kidney dialysis services.

SSB 5569 defines a “temporary emergency situation” to include the following:

Substitute Senate Bill 5569

(2) A temporary emergency situation is defined to include:

- (a) Natural disasters, such as earthquakes, floods, fires, or snowstorms that limit or restrict access to one or more kidney disease centers thereby creating a need for additional capacity at other centers;
- (b) Power outages or water system shutdowns;
- (c) Mold remediations or other physical plant issues that would put patient safety at risk;
- (d) Staffing shortages that require kidney disease center reconfiguration to facilitate delivery of dialysis services as long as the facility does not exceed the number of patients served at the time of the exemption request. If granted, an exemption under this subsection (2) (d) is valid for 90 days, and may be extended at 90-day increments at the discretion of the department; and
- (e) Any additional temporary emergency situations as included by the department in rule.

At a minimum, a definition of temporary emergency situations consistent with the events described above in SSB 5569 (2)(a)-(d) should be included in the Washington Administrative Code (“WAC”) for maximum clarity.

SSB 5569 (2)(e) asks for the Department to include a list of any additional temporary emergency situations in the final rules. FMCNA recommends the Department add the following events to the temporary emergency situation definition:

- + Disease outbreaks such as influenza, COVID-19, or other infectious diseases that require redistribution and separation of dialysis patients among facilities to accommodate quarantine and isolation needs, social distancing, or other factors necessary to prevent transmission and exposure.
- + Severe disruption to transportation infrastructure like roads, bridges, or public transit that severely limits patient access to facilities.
- + Any state or federal emergency declaration issued by a state or federal entity with authority that has a direct impact on availability, operations, or patient access to kidney

dialysis services in Washington State. This includes declarations related to public health emergencies, disasters, and other state or federally declared emergencies.

Recommendation 2. Define which facilities are considered to be an ‘affected facility’ when a temporary emergency station exemption is invoked.

SSB 5569’s definition of temporary emergency situations recognizes that an emergency situation has the potential to affect multiple facilities. Therefore, it is important to define what is considered an ‘affected facility’ when a temporary emergency station exemption is invoked.

In the case of “staffing shortage” emergency situations, this will only involve the facility requesting the exemption stations, as there is a patient limitation requirement unique to “staffing shortage” emergencies. However, other emergency situations such as natural disasters are likely to significantly impact multiple facilities. For example, a natural disaster that disrupts Facility A may necessitate full or partial closure of operations and patients being transferred to receive care at Facility B and Facility C. Facility B and Facility C will have to submit separate exemption requests to the Department to receive approval to operate additional temporary stations. In this example, Facility B and Facility C are clearly ‘affected facilities’, as both facilities are requesting additional stations. Yet, the rules should be designed to also define Facility A from this example as an ‘affected facility’. This is important, as all three facilities in the example must be recognized when evaluating other sections of the kidney dialysis rules. For example, Facility A’s station use rate will be 0 patients per station which could impact the Department’s nonspecial circumstance needs assessment under WAC 246-310-812. Thus, failure to appropriately define which facilities meet a definition of ‘affected facility’ could have a disruptive impact on existing rules that include measures of facility capacity, based on number of patients and station counts, which are used to determine whether a planning area meets requirements of WAC 246-310-212(5).

Recommendation 3. Exclude temporary emergency stations from need calculations in WAC 246-310-812(4).

The existing nonspecial numeric need methodology in WAC 246-310-812 determines projected need by comparing the current number of CN-approved stations to the projected future patient volume.

[Existing] WAC 246-310-812

(4)(d): To determine the net station need for a planning area, subtract the number calculated in (c) of this subsection from the total number of certificate of need approved stations located in the planning area. This number does not include the one department recognized exempt isolation station defined in WAC 246-310-800(9). For example, a kidney dialysis facility that is certificate of need approved and certified for eleven stations would subtract the one exempt isolation station and use ten stations for the methodology calculations.

However, if facilities expand capacity during temporary emergency situations, it could artificially suppress the projected need, even though those stations are only temporary.

FMCNA recommends that WAC 246-310-812 be amended to specify that any stations added by a kidney dialysis facility under the temporary emergency exemption in SSB 5569 be excluded from the “certificate of need approved stations” count used in the need methodology calculations in WAC 246-310-812(4).

This proposed clarification to the rules will preserve the integrity of the long-term capacity planning process while allowing necessary flexibility to meet patient surge needs during temporary emergency situations. FMCNA believes exempting temporary emergency stations from the existing inventory used to calculate projected need will appropriately implement the provisions of SSB 5569 without undermining the effectiveness of the certificate of need program in ensuring sustainable access to care.

Recommendation 4. Assure that station use rates at affected facilities invoking the temporary emergency exemption are not a barrier to additional new stations needed under WAC 246-310-812.

The rules in WAC 246-310-812(5)-(6) currently require facilities in a planning area to meet minimum utilization thresholds before additional stations can be approved based on projected need, except if other considerations specified in (5)(a)-(b) or (6)(a)-(b) are met. However, utilization rates may be impacted if a facility has expanded capacity under the new temporary exemption law or is otherwise impacted by an emergency situation, as noted above.

FMCNA recommends the Department amend the rules to specify that a facility’s station use rate cannot be a barrier to approval of additional stations needed under WAC 246-310-812 if the facility has been an ‘affected facility’ during the time period of the applicable ESRD modality report for the review cycle.

This rule change can be enacted by simply adding a new (5)(c) and new (6)(c) that states the Department would find a facility has met the occupancy standard if it is an ‘affected facility’ during the time period of the applicable ESRD modality report.

With respect to other considerations under WAC 246-310-812(5)-(6), FMCNA recommends that temporary stations be excluded from the Department’s evaluation of (5)(a) and (6)(a) whether “All stations for a facility have been in operation for at least three years”.

Recommendation 5. Exclude facilities affected by non-staffing shortage emergencies from special circumstance expansions in WAC 246-310-818. However, this exemption should not apply to facilities approved for temporary emergency stations for staffing shortage

emergencies; such facilities should be allowed to apply for additional stations under WAC 246-310-818, where the additional, temporary stations are not counted.

The existing special circumstance numeric need methodology in WAC 246-310-818 specifies patient per station use rates required for the Department to approve a facility to add +1/+2 stations.

Because of the impact of patient transfers in non-staffing shortage emergencies, any facility that meets the definition of ‘affected facility’ during the most recent six consecutive month period preceding the letter of intent submission date should be disqualified for applying for special circumstance +1/+2 stations during the next concurrent review cycle.

SSB 5569(2)(d) places a limitation on staffing shortage emergency requests that the “facility does not exceed the number of patients served at the time of the exemption request.” Therefore, a facility granted a temporary exemption solely due to a staffing shortage emergency should still be allowed to apply for a +1/+2 special circumstance request with a recognition that the maximum patient census allowed for the Department to evaluate the special circumstance request will be the number of patients served, and the number of stations at the time of the exemption request.

In the Department’s review of +1/+2 special circumstance requests by facilities that were granted a temporary exemption solely due to a staffing shortage emergency, the temporary stations should be excluded from the special circumstance need methodology calculations established in WAC 246-310-818.

Recommendation 6. Adopt rules to assure that requests for temporary emergency exemptions may be filed at any time.

The new emergency exemption law allows capacity expansion outside the normal planning process. However, the concurrent review cycle rules do not currently reflect exceptions for emergency situations.

FMCNA recommends the Department adopt rules to assure that requests for temporary emergency exemptions may be filed at any time. The rules should also clarify there is no conflict between temporary emergency exemptions and the concurrent review cycles established in WAC 246-310-806. This would codify that the new exemption process can operate independently of the normal planning timelines.

Recommendation 7. Adopt rules to clarify that a temporary closure of operations at a facility due to an event that qualifies as a temporary emergency does not extinguish that facility’s certificate of need.

In the case of temporary emergency situations, a facility may be compelled to close temporarily for health and safety reasons. However, current rules have no exception for those types of

situations, and as a result it could result in partial or full revocation of the facility's certificate of need.

FMCNA recommends that the Department adopt rules to specify that a kidney dialysis facility's certificate of need will remain intact if the facility is forced to temporarily close operations due to circumstances that qualify as a temporary emergency situation.

Ensuring facilities can restore capacity after a temporary emergency-related closure will support continuity of care without unnecessary regulatory delays. FMCNA urges the Department to preserve a facility's certificate of need in these situations.

Recommendation 8. Add temporary emergency exemptions data reporting requirements to WAC 246-310-803.

To improve transparency in implementation of SSB 5569, FMCNA recommends additional data reporting rules under WAC 246-310-803 be added requiring the Department to publicly post temporary emergency exemption materials on its website within a defined timeframe (e.g. 5 working days, 10 working days).

Specifically, the Department should be required to publish on its website the following within a defined timeframe (e.g. 5 working days, 10 working days) of receipt or determination:

- Kidney dialysis facility's initial exemption request.
- The Department's exemption determination.

Requiring timely posting of exemption requests and determinations will support public awareness and oversight of how the new statutory authority is applied. It will also provide transparency needed to support other facilities' planning efforts that may be impacted if a nearby facility applies for a temporary emergency exemption.