November 20, 2023

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

RE: Rules to Implement SSB5569

Dear Messers Valore and Hernandez:

Northwest Kidney Centers (NKC) has actively participated in the CR101 process to implement SSB5569. As agreed at the October workshop, NKC's consultant (Jody Carona, Health Facilities Planning & Development) and the Fresenius consultant (Hunter Plumer, Health Trends) were to each individually develop hypothetical scenarios to model, and then conference to review each scenario and its implications. That process happened, and I understand that the development, sharing, and subsequent discussion was both productive and insightful.

We have also been provided with a copy of the Fresenius November 13 written comments and proposed rule changes. It is NKC's position that a number of Fresenius' proposed changes exceed the scope of SB5569 and, if adopted, could have a profound impact on future CN reviews. Because the Program has elected to focus its rulemaking on only the changes needed to implement SSB5569, we respectfully request that the Fresenius changes that exceed scope be put aside until the larger review of the 2018 dialysis CN rules is undertaken.

Our comments and rationale are attached. We have shared our comments with Fresenius. We will be prepared to discuss it at the November 28 meeting.

Thank you.

Sincerely,

Robin Larmer
Vice President of Legal Affairs and Chief Compliance Officer

Northwest Kidney Centers
CR101 Written Comments Regarding SSB 5569
November 20, 2023

Background

Both NKC and Fresenius (FMCNA) largely developed similar scenarios related to a facility being closed or limited by a natural disaster or a physical plant failure. Interestingly, and related to emergency staffing, NKC and FMCNA each independently developed scenarios wherein a provider is operating at relatively high occupancy at the time of the request for emergency stations due to staffing. Current rules are predicated on the assumption that existing urban facilities operate three shifts per day, six days per week (18 shifts per week). The assumption under the emergency rules is that, most likely, the evening shift will be eliminated (so moving from 18 shifts per week to 12) with more stations available for patients to dialyze during the two daytime shifts. While the notion of a high occupancy facility needing an emergency exemption for staffing was not contemplated during the legislative process, the hypothetical scenario exercise did identify this as an area needing to be addressed, and a considerable portion of this letter focuses on a request for a staffing emergency, and the impact on other providers operating in the same or adjacent planning area.

In addition, at the last meeting the question was posed about whether CMS would waive its physical plant conditions of participation for the period of the declared emergency. This is critical to understand. Given that current CN dialysis rules, effective January 1, 2018, limit both the maximum treatment floor area, and the number of completed or even shelled stations to two (see WAC 246-310-800 (11) (c)), the ability to add stations may be a limiting factor.

Response to FMCNA Scenarios:

FMCNA's November 13 letter puts forth three non-special circumstance scenarios and two special circumstance scenarios. We offer our response on each scenario below:

Non-Special Circumstance Scenario 1

NKC concurs with FMCNA that a facility (Facility B) that is closed and 100% of its patients relocated due to a natural disaster should not preclude other facilities located in the planning area from pursuing new stations or special circumstance stations ***as long as*** those other facilities meet the occupancy requirement. Specifically, if they added emergency stations in response to the Facility B closure, they met the requirement with their CN recognized station count prior to the closure or scaled back operation of Facility B. In addition, we would expect that these other facilities meet all other requirements in WAC for expansion.

In the scenario outlined by FMCNA, Facility B closed, and Facility A added 7 stations. Facility A had been operating above the 4.5 patients per station threshold for adding new stations before adding temporary stations. FMCNA points out that the data to support the facility's occupancy may not be available in time in the Network's quarterly reporting. This can be resolved in the same manner as the current special circumstance occupancy data is secured: the Network can provide it outside of the normal quarterly data updates.

Non-Special Circumstance Scenario 2: NKC respectfully disagrees with FMCNA. As we understand this scenario, Facility A had occupancy below 4.5 patients per station before the emergency. We do not concur that it should be "cleared" to apply for stations using calculations based on the count of patients being temporarily relocated while excluding the temporary stations. Operating below 4.5 is a "non-

starter" for CN application submittal under normal events and should continue to be so under natural disaster or staffing emergency. Using the temporarily relocated patients to calculate occupancy is not appropriate since these patients will likely be relocated back to the other facility following the emergency, reducing the facility again below the required occupancy.

NKC also disagrees with FMCNA's statement that WAC 246-310-812 (5)(c) should waive the patient occupancy requirements for all temporary emergencies. Requesting and being granted a temporary emergency station exemption should not open the door to being able to submit for new stations which a facility is not otherwise eligible to pursue.

Non-Special Circumstance Scenario 3: As outlined above**,** NKC does not support the addition of stations to a facility that secured an emergency station waiver due to staffing and then added stations and contracted shifts. We strongly support staffing emergencies being treated differently than natural disasters and physical plant failures (fire, water treatment system failure, etc.). In Non-Special Circumstance #3, the reality is that Facility A, which is experiencing a staffing shortage, needs additional stations only because it intends to close shifts. In NKC's experience some number of patients will seek to relocate to another facility either because they attend school or work during the day, or otherwise prefer or need the shift that is being closed, and census will decline. Further, the reason for the staffing emergency, especially when the other two facilities in the same planning area are not experiencing one, should be considered.

The reality that a facility could add new patients during its staffing emergency was not contemplated during the legislative session. It's even more disconcerting in the Scenario 3 example, because the other open facility continues to staff three shifts per day. With the transfer of patients needing the evening shift, Facility A can add morning and day slots for new patients. For example, a facility that loses 10 patients due to shift closures could add 10 new patients to its other shifts and remain at the number of patients at the time of securing the emergency staffing exemption. This was not the intent.

Special Circumstance Scenarios 1 and 2: NKC also respectfully disagrees with the ability for a facility operating under a staffing emergency to file a special circumstances application. Current rules require that a facility operate above 5.0 patients per station (assuming three shifts per day, six days per week) for a period of at least six consecutive months prior to the month of the letter of intent. Applications are submitted 30 days after the letter of intent, and the review process takes about 6-9 months. All in all, today, the process easily exceeds one year. This timeline conflicts with both the guiding statute and the emergency exemption rules because the additional stations added during the staffing emergency exemption are temporary and short term. Calculating occupancy utilizing all patients but only the permanent stations (not those added during the emergency) will likely lead to a misleading higher occupancy that will resolve when the staffing emergency is addressed. Again, and for the reasons noted above, the facility is likely to lose a percentage of the patients that it had on service as of the date it secured the staffing emergency, because of the reduction in shifts.

We also do not support shortening the period for eligibility to less than six months. The real fix here has to be a redo of the special circumstance rules and timelines in total, which is necessary to address the promise of the special circumstance language. Per the Department, we understand this fix is beyond the scope of SSB5569.

NKC's proposed language for the non-special and special circumstance rules are attached. For reader ease, we used the DOH workbook and simply added a new column entitled "NKC Comments."

Per DOH Workbook for November 28 Rule Workshop					
WAC Section	**Public comment: Draft rule language**	**CN Response**	**Draft Language**	**Action items**	**NKC Comments**
WAC 246-310-800 Kidney disease treatment center – Definitions	No comments		No draft language added to section	Uses "center" rather than "facility" for section title. Should all references to "Northwest Renal Network" be amended to state "Comagine?"	May need to consider modifying definitions for "end of year data" and "end of year in-center patients" if an emergency was in place.
WAC 246-310-803 Kidney disease treatment facilities – Data reporting requirements	No comments		No draft language added to section	None	A requirement to submit the number of shifts being operated should be required for those operating for each month a provider is operating under an emergency exception. This is necessary to understand actual occupancy per rule (i.e.: 4.8 patients per station or 18 shifts per week).
WAC 246-310-806 Kidney disease treatment facilities – concurrent review Cycles	No comments		No draft language added to Section	None	None
WAC 246-310-809 One-time exempt isolation station reconciliation	No comments		No draft language added to Section	None	None
WAC 246-310-812 Kidney disease treatment facilities – Methodology	No comments		No draft language added to section	Will need to update reference to new standalone temporary emergency situation section.	In addition to 5 (a), language should be considered under WAC 246-310-812 5) (b) to address a facility operating

Per DOH Workbook for November 28 Rule Workshop					
WAC Section	**Public comment: Draft rule language**	**CN Response**	**Draft Language**	**Action items**	**NKC Comments**
				Come back to 5(a) for next workshop	under an emergency
WAC 246-310-815 Kidney disease treatment facilities – Financial feasibility	No comments		No draft language added to section	None	None
WAC 246-310-818 Special Circumstances	No comments		No draft language added to section		Language should specifically state that providers operating under an emergency are ineligible unless they had met the standard for the six months prior to requesting and receiving the emergency exemption
WAC 246-310-821 Kidney disease treatment facilities- Standards for planning areas without an existing facility	No comments		No draft language added to section	None	None
WAC 246-310-824 Kidney disease treatment centers - exceptions	No comments		No draft language added to section	Uses "center" rather than "facility" for section title.	No changes to section, other than that noted in Action Items

Per DOH Workbook for November 28 Rule Workshop					
WAC Section	**Public comment: Draft rule language**	**CN Response**	**Draft Language**	**Action items**	**NKC Comments**
NEW SECTION WAC 246-310-825 Temporary Emergency Situation Exemption	No comments	**WAC 246-310-825(1)(b)** At 10/17 workshop, group decided to eliminate current temporary emergency situation language in WAC 246-310-825(1)(b) regarding disruption due to infrastructure issues and replace with language granting department discretion to determine whether event constitutes "temporary emergency situation."	**WAC 246-310-825(1)(b)** Removed current 246-310-825(1)(b) and replaced with: (b) Any other temporary emergency situations that in the department's discretion constitute a "temporary emergency situation."		None
		WAC 246-310-825(2)(a) At 10/17 workshop, the group proposed amending current definition of "staffing shortage" at 246-310-825(2)(a). Group noted that it is difficult to define due to differing acuity.	**WAC 246-310-825(2)(a)** Removed current 246-310-825(2)(a) and replaced with: (a) "Staffing shortage" means that the kidney disease treatment center does not have sufficient staff to safely provide treatment.		None
WAC 246-310-827 Kidney disease treatment facilities – superiority criteria	No comments.		No draft language added to section	None	None

Per DOH Workbook for November 28 Rule Workshop					
WAC Section	**Public comment: Draft rule language**	**CN Response**	**Draft Language**	**Action items**	**NKC Comments**
WAC 246-310-830 Kidney disease treatment facilities—Relocation of facilities	No comments.		No draft language added to section	None	Should consider, whether at (4), a facility closed or limited due to natural disaster or physical plant deficiency should be allowed to relocate in the same planning area and with the same number of stations without prior CN review, even if in operation under current ownership less than 5 years.
WAC 246-310-833 One-time state border kidney dialysis facility station relocation	No comments.		No draft language added to section	None	None