



November 21, 2023

Via Email

Washington State Department of Health Certificate of Need Program Ross Valore, Executive Director Eric Hernandez, Manager 111 Israel Road SE Tumwater, WA 98501

Dear Mr. Valore and Mr. Hernandez,

Thank you for 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.

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

If you have any questions regarding these comments, please feel free to contact me at (724) 462-7102 or jenna.gilbreath@davita.com.

Sincerely,

Jenna Gilbreath

Director – Special Projects | North Star Division





DaVita's Written Comments for Rulemaking Workshop #3 on November 28, 2023.

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

DaVita supports the proposed language included in the DRAFT_ESRD_Rule_Language.pdf document distributed on November 1st for the following statutes: WAC 246-310-812 (4), WAC 246-310-812 (5)(a), WAC 246-310-812 (6)(a)

DaVita does not support the language proposed as WAC 246-310-812(5)(c) as this exception could artificially clear the planning areas for new nonspecial stations if there are facilities affected by a temporary emergency situation, regardless of whether or not the facility met the threshold criteria prior to the temporary emergency situation. There is risk that a provider could utilize temporary emergency situations to bypass the criteria in WAC 246-310-812(5) that would have otherwise prevented new nonspecial stations from being approved in the planning area.

DaVita also acknowledges that there are going to be cases where a temporary emergency situation causes a clinic to fall below utilization thresholds, preventing new nonspecial stations from being approved, which would have otherwise not been the case had the temporary emergency situation not occurred. Therefore, DaVita does support that language be added to WAC 246-310-812(5) to address impacts in patient census data, and subsequently, station occupancy rates that may occur from temporary emergency situations. However, the language introduced should not result in a change of status as to whether or not the facility clears the department's review as a result of the temporary emergency situation.

The following hypothetical scenarios highlights instances where the proposed language in WAC 246-310-812(5)(c) does flip the status of a facility clearing the Department's review. These scenarios also illustrate that the status could flip if there is no language added at all that addresses the impacts of a temporary emergency situation.

Scenario A: In this scenario, Facility A is below the 4.5 utilization standard prior to the temporary emergency situation, which would have prevented new nonspecial stations from being approved. After the temporary emergency situation, the language proposed in WAC 246-310-812(5)(c) flips all facilities to clear the Department's review and allows new nonspecial stations to be approved. The presence of the temporary emergency situation and the proposed language in WAC 246-310-812(5)(c) has a direct affect in changing the status of whether or not nonspecial stations can be approved or not.

	Facility A	Facility B	Facility
CN Permanent Stations	10	10	10
# of patients (assuming	35	50	55
no temp emergency)			
Patient per Station	3.5	5.0	5.5
Utilization (assuming to			
temp emergency)			





Affected by Temporary Emergency?	Yes (Stations Added)	Yes (Temp Closure)	No
Temporary # of Patients	50	-50	0
Total Patients (what	85	0	55
would appear in			
modality report)			
Patient per Station	8.5	0.0	5.5
Utilization (Total			
Patients Divided by			
Permanent Stations)			
Clear Department's	No (below 4.5	Yes (above 4.5	Yes (above 4.5
review prior to temp	standard)	standard)	standard)
emergency			
Clear Department's	Yes (above 4.5	No (below 4.5	Yes (above 4.5
review after temp	standard)	standard)	standard)
emergency without			
proposed WAC 246-310-			
812(5)(c)			
Clear Department's	Yes (affected facility)	Yes (affected facility)	Yes (above 4.5
review after temp			standard)
emergency with			
proposed WAC 246-310-			
812(5)(c)			

Scenario B: In this scenario, all facilities are above the 4.5 utilization standard prior to the temporary emergency situation, which would have allowed new nonspecial stations to be approved. After the temporary emergency situation, Facility B falls below the utilization standard which would prevent new nonspecial stations from being approved if there were no statute language included to address the impact on station utilization from temporary emergency situations. In this case, not addressing the impacts of the temporary emergency situation within WAC 246-310-812(5) has a direct affect in changing the status of whether or not nonspecial stations can be approved or not.

	Facility A	Facility B	Facility
CN Permanent Stations	10	10	10
# of patients (assuming	50	50	55
no temp emergency)			
Patient per Station	5.0	5.0	5.5
Utilization (assuming to			
temp emergency)			
Affected by Temporary	Yes (Stations Added)	Yes (Temp Closure)	No
Emergency?			
Temporary # of Patients	50	-50	0





Total Patients (what	85	0	55
would appear in			
modality report)			
Patient per Station	8.5	0.0	5.5
Utilization (Total			
Patients Divided by			
Permanent Stations)			
Clear Department's	Yes (above 4.5	Yes (above 4.5	Yes (above 4.5
review prior to temp	standard)	standard)	standard)
emergency			
Clear Department's	Yes (above 4.5	No (below 4.5	Yes (above 4.5
review after temp	standard)	standard)	standard)
emergency without			
proposed WAC 246-310-			
812(5)(c)			
Clear Department's	Yes (affected facility)	Yes (affected facility)	Yes (above 4.5
review after temp			standard)
emergency with			
proposed WAC 246-310-			
812(5)(c)			

DaVita proposes the following language addition to WAC 246-310-812(5)(b) and WAC 246-310-812(6)(b) to address the impacts of a temporary emergency situations without allowing facilities to clear the Department's review simply because they are affected by a temporary emergency situation, highlighted in red below:

WAC 246-310-812 (5)(b): Certificate of need approved stations for a facility have not become operational within the timeline as represented in the approved application. For example, an applicant states the stations will be operational within eight months following the date of the certificate of need approval. The eight months would start from the date of an uncontested certificate of need approval. If the certificate of need approval is contested, the eight months would start from the date of the final department or judicial order. However, the department, at its sole discretion, may approve a one-time modification of the timeline for purposes of this subsection upon submission of documentation that the applicant was prevented from meeting the initial timeline due to circumstances beyond its control.

Both resident and nonresident patients using the kidney dialysis facility are included in this calculation. Data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date.

(i) If a facility was affected by a temporary emergency situation, as defined in RCW 70.38.280, at the time of the patient census estimates presented in the most recent quarterly modality report from the ESRD Network as of the letter of intent submission date, then the census data for the affected facility must come from the quarterly modality report from the Northwest Renal Network that directly precedes the date that the temporary emergency situation exemption request was submitted to the department for the affected facility.