FRESENIUS MEDICAL CARE

September 25, 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 initial draft set of proposed rule changes sent on September 8, 2023 when notifying stakeholders of the upcoming public rules workshops to be held on September 28th and October 19th.

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

COLOR LEGEND

	Department's initial set of proposed rule changes sent on September 8, 2023.
	FMCNA's proposed supplemental rule changes.
	FMCNA comments explaining rationale for proposed rule changes.

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246-310-800 Kidney disease treatment centers—Definitions.

The definitions in this section apply to WAC 246-310-800 through **246-310-833**, unless the context clearly indicates otherwise:

(1) "Affiliate" or "affiliated" means:

(a) Having at least a ten percent but less than one hundred percent ownership in a kidney dialysis facility;

(b) Having at least a ten percent but less than one hundred percent financial interest in a kidney dialysis facility; or

(c) Three years or more operational management responsibilities for a kidney dialysis facility.

(2) "Base year" means the most recent calendar year for which December 31 data is available as of the letter of intent submission date from the *Northwest Renal Network's Modality Report*.

(3) "Capital expenditures," as defined by *Generally Accepted Accounting Principles* (GAAP), means expenditures made to acquire tangible long-lived assets. Long-lived assets represent property and equipment used in a company's operations that have an estimated useful life greater than one year. Acquired long-lived assets are recorded at acquisition cost and include all costs incurred necessary to bring the asset to working order. Capital expenditure includes:

(a) A force account expenditure or acquisition (i.e., an expenditure for a construction project undertaken by a facility as its own contractor).

(b) The costs of any site planning services (architect or other site planning consultant) including, but not limited to, studies, surveys, designs, plans, working drawings, specifications, and other activities (including applicant staff payroll and employee benefit costs, consulting and other services which, under GAAP or Financial Accounting Standards Board (FASB) may be chargeable as an operating or nonoperating expense).

(c) Construction cost of shelled space.

(d) Building owner tenant improvements including, but not limited to: Asbestos removal, paving, concrete, contractor's general conditions, contractor's overhead and profit, electrical, heating, ventilation and air conditioning systems (HVAC), plumbing, flooring, rough and finish carpentry and millwork and associated labor and materials, and utility fees.

(e) Donations of equipment or facilities to a facility.

(f) Capital expenditures do not include routine repairs and maintenance costs that do not add to the utility of useful life of the asset.

(4) "Concurrent review" means the process by which applications competing to provide services in the same planning area are reviewed simultaneously by the department.

(5) "Dialysis facility report (DFR)" means the kidney dialysis facility reports produced annually for Centers for Medicare and Medicaid Services (CMS). The DFR is provided to individual dialysis facilities and contains summary data on each facility compiled from multiple sources. The DFR facilitates comparison of patient characteristics, treatment patterns, transplantation rates, hospitalization rates, and mortality rates to local and national averages.

(6) "Dialysis facility compare (DFC) report" means the kidney dialysis facility compare quarterly report that is produced by CMS and posted on the medicare DFC website. This report provides information about statistically measurable practice patterns in kidney disease

treatment facilities including, but not limited to, mortality, hospitalization, late shifts, and availability of home training.

(7) "End-of-year data" means data contained in the fourth quarter modality report or successor report from the Northwest Renal Network.

(8) "End-of-year in-center patients" means the number of in-center hemodialysis (HD) and self-dialysis training patients receiving in-center kidney dialysis at the end of the calendar year based on end-of-year data.

(9) "Exempt isolation station" means one certificate of need approved certified station per facility dedicated to patients requiring medically necessary isolation. This station may not be used for nonisolation treatments. This one approved station is included in the kidney dialysis facility's total CMS certified station count. However, for purposes of certificate of need, this one isolation station is not included in the facility's station count for projecting future station need or in calculating existing station use. Providers may operate more than one isolation station, but only one is excluded from the facility's station count for purposes of projecting future station need and in calculating existing station use.

(10) "Kidney disease treatment center" or "kidney dialysis facility" means any place, institution, building or agency or a distinct part thereof equipped and operated to provide services, including outpatient dialysis. In no case will all stations at a given kidney disease treatment center or kidney dialysis facility be designated as self-dialysis training stations. For purposes of these rules, kidney disease treatment center and kidney dialysis facility have the same meaning.

(11) "Maximum treatment floor area square footage" means the sum of (a), (b), (c), and (d) of this subsection:

(a) One hundred fifty square feet multiplied for each general use in-center station and each nonisolation station;

(b) Two hundred square feet multiplied for each isolation station and each permanent bed station as defined in subsection (14) of this section;

(c) Three hundred square feet for future expansion of two in-center treatment stations; and

(d) Other treatment floor space is seventy-five percent of the sum of (a), (b), and (c) of this subsection.

As of the effective date of these rules, maximum treatment floor area square footage identified in a successful application cannot be used for future station expansion, except as provided in (c) of this subsection. For example, the applicant may use the maximum allowable treatment floor area square footage. The number of stations may include one isolation station, one permanent bed station, eight general use in-center stations, two future expansion stations, and maximum other treatment floor space. In this example, the total maximum treatment floor area square footage in this example would equal three thousand three hundred twenty-five square feet.

(12) "Operational" means the date when the kidney dialysis facility provides its first dialysis treatment in newly approved certificate of need stations, including relocated stations.

(13) "Patients per station" means the reported number of in-center patients at the kidney dialysis facility divided by counted certificate of need approved stations. The results are not rounded up. For example, 4.49 is not rounded to 4.5.

(14) "Permanent bed station" means a bed that would commonly be used in a health care setting.

(15) "Planning area" or "service area" means an individual geographic area designated by the department for which kidney dialysis station need projections are calculated. For purposes of kidney dialysis projects, planning area and service area have the same meaning. Each county is considered a separate planning area, except for the planning subareas identified for King, Snohomish, Pierce, and Spokane counties. If the United States Postal Service (USPS) changes zip codes in the defined planning areas, the department will update areas to reflect the revisions to the zip codes to be included in the certificate of need definitions, analyses and decisions. Post office boxes are not included.

(a) King County is divided by zip code into twelve planning areas as follows:

KING ONE	KING TWO	KING THREE
98028 Kenmore	98101 Business District	98070 Vashon
98103 Green Lake	98102 Eastlake	98106 White Center/West Seattle
98105 Laurelhurst	98104 Business District	98116 Alki/West Seattle
98107 Ballard	98108 Georgetown	98126 West Seattle
98115 View Ridge/Wedgwood	98109 Queen Anne	98136 West Seattle
98117 Crown Hill	98112 Madison/Capitol Hill	98146 West Seattle
98125 Lake City	98118 Columbia City	98168 Riverton
98133 Northgate	98119 Queen Anne	
98155 Shoreline/Lake Forest Park	98121 Denny Regrade	
98177 Richmond Beach	98122 Madrona	
98195 University of Washington	98134 Harbour Island	
	98144 Mt. Baker/Rainier Valley	
	98199 Magnolia	

KING FOUR	KING FIVE	KING SIX
98148 SeaTac	98003 Federal Way	98011 Bothell
98158 SeaTac	98023 Federal Way	98033 Kirkland
98166 Burien/Normandy Park		98034 Kirkland
98188 Tukwila/SeaTac		98052 Redmond
98198 Des Moines		98053 Redmond
		98072 Woodinville
		98077 Woodinville

KING SEVEN	KING EIGHT	KING NINE
98004 Bellevue	98014 Carnation	98055 Renton
98005 Bellevue	98019 Duvall	98056 Renton
98006 Bellevue	98024 Fall City	98057 Renton
98007 Bellevue	98045 North Bend	98058 Renton
98008 Bellevue	98065 Snoqualmie	98059 Renton
98039 Medina	98027 Issaquah	98178 Skyway
98040 Mercer Island	98029 Issaquah	
	98074 Sammamish	
	98075 Sammamish	

KING TEN	KING ELEVEN	KING TWELVE
98030 Kent	98001 Auburn	98022 Enumclaw
98031 Kent	98002 Auburn	
98032 Kent	98010 Black Diamond	
98038 Maple Valley	98047 Pacific	
98042 Kent	98092 Auburn	
98051 Ravensdale		

(b) Pierce County is divided into five planning areas as follows:

PIERCE ONE	PIERCE TWO	PIERCE THREE
98354 Milton	98304 Ashford	98329 Gig Harbor
98371 Puyallup	98323 Carbonade	98332 Gig Harbor
98372 Puyallup	98328 Eatonville	98333 Fox Island
98373 Puyallup	98330 Elbe	98335 Gig Harbor
98374 Puyallup	98360 Orting	98349 Lakebay
98375 Puyallup	98338 Graham	98351 Longbranch
98390 Sumner	98321 Buckley	98394 Vaughn
98391 Bonney Lake		

PIERCE FOUR	PIERCE FIVE

98402 Tacoma	98303 Anderson Island
98403 Tacoma	98327 DuPont
98404 Tacoma	98387 Spanaway
98405 Tacoma	98388 Steilacoom
98406 Tacoma	98430 Tacoma
98407 Ruston	98433 Tacoma
98408 Tacoma	98438 Tacoma
98409 Lakewood	98439 Lakewood
98416 Tacoma	98444 Parkland
98418 Tacoma	98445 Parkland
98421 Tacoma	98446 Parkland
98422 Tacoma	98447 Tacoma
98424 Fife	98467 University Place
98443 Tacoma	98498 Lakewood
98465 Tacoma	98499 Lakewood
98466 Fircrest	98580 Roy

(c) Snohomish County is divided into three planning areas as follows:

SNOHOMISH ONE	SNOHOMISH TWO	SNOHOMISH THREE
98223 Arlington	98201 Everett	98012 Mill Creek/Bothell
98241 Darrington	98203 Everett	98020 Edmonds/Woodway
98252 Granite Falls	98204 Everett	98021 Bothell
98271 Tulalip Reservation/ Marysville	98205 Everett	98026 Edmonds
98282 Camano Island	98208 Everett	98036 Lynnwood/Brier
98292 Stanwood	98251 Gold Bar	98037 Lynnwood
	98224 Baring	98043 Mountlake Terrace
	98258 Lake Stevens	98087 Lynnwood
	98270 Marysville	98296 Snohomish
	98272 Monroe	
	98275 Mukilteo	
	98288 Skykomish	
	98290 Snohomish	
	98294 Sultan	

(d) Spokane County is divided into two planning areas as follows:

SPOKANE ONE	SPOKANE TWO
99001 Airway Heights	99003 Chattaroy
99004 Cheney	99005 Colbert
99011 Fairchild Air Force Base	99006 Deer Park
99012 Fairfield	99009 Elk
99016 Greenacres	99021 Mead
99018 Latah	99025 Newman Lake
99019 Liberty Lake	99026 Nine Mile Falls
99022 Medical Lake	99027 Otis Orchards
99023 Mica	99205 Spokane
99030 Rockford	99207 Spokane
99031 Spangle	99208 Spokane
99036 Valleyford	99217 Spokane
99037 Veradale	99218 Spokane
99201 Spokane	99251 Spokane
99202 Spokane	
99203 Spokane	
99204 Spokane	
99206 Spokane Valley	
99212 Spokane Valley	
99216 Spokane/Spokane Valley	
99223 Spokane	
99224 Spokane	

(16) "Projection year" means the fifth calendar year after the base year. For example, reviews using 2015 end-of-year data as the base year will use 2020 as the projection year.

(17) "Quality incentive program" or "QIP" means the end-stage renal disease (ESRD) quality incentive program (QIP) administered by the Centers for Medicare and Medicaid Services (CMS). The QIP measures kidney dialysis facility performance based on outcomes assessed through specific performance and quality measures that are combined to create a total performance score (TPS). The QIP and TPS are updated annually and are publicly available on the CMS DFC website.

(18) "Quintile" means any of five groups into which a population can be divided according to the distribution of values of a particular variable.

(19) "Resident in-center patients" means in-center hemodialysis (HD) patients who reside within the planning area. If more than fifty percent of a kidney dialysis facility's patients reside outside Washington state, these out-of-state patients would be considered resident in-center patients.

(20) "Shelled space" means space that is constructed to meet future needs; it is a space enclosed by a building shell but otherwise unfinished inside unless the space designated for future needs is part of an existing, finished building prior to an applicant's proposed project. In that case, there is no requirement to degrade the space. The shelled space may include:

(a) Electrical and plumbing that will support future needs;

(b) Insulation;

(c) Sheet rock that is taped or other similar wall coverings that are otherwise unfinished; and

(d) Heating, ventilation, and air conditioning.

(21) "Training services" means services provided by a kidney dialysis facility to train patients for home dialysis. Home training spaces are not used to provide in-center dialysis treatments. Spaces used for training are not included in the facility's station count for projecting future station need or in calculating existing station use. Stations previously designated as "training stations" may be used as in-center dialysis stations and will continue to be included in the facility's current station count for projecting future station need or in calculating existing station use. For the purpose of awarding the point for home training in the superiority criteria section (WAC **246-310-823**), training services include the following:

(a) Home peritoneal dialysis (HPD); and

(b) Home hemodialysis (HHD).

246-310-803 Kidney disease treatment facilities—Data reporting requirements.

(1) By February 15th or the first working day thereafter of each year, each provider will electronically submit the following data elements for each of its kidney dialysis facilities in the state of Washington and each out-of-state kidney dialysis facility that might be used in an application review during the next year (an out-of-state kidney dialysis facility may be used as one of the three closest facilities for a future project during the next year pursuant to WAC **246-310-827**):

(a) Cost report data for the most recent calendar or fiscal year reporting period for which data is available reported to the Centers for Medicare and Medicaid Services (CMS) that is used to calculate net revenue per treatment; and

(b) Data reported to providers by CMS for the most recent calendar or fiscal year reporting period for which data is available to identify the percentage of nursing home patients and the average number of comorbid conditions.

(2) A provider's failure to submit complete data elements identified in subsection (1)(a) and (b) of this section in the format identified by the department for a facility by the deadline in subsection (1) of this section or whose data for a facility is not complete on the DFC report or QIP report (medicare website) will result in automatic rejection of concurrent review applications for that provider until the following year's data report deadline unless an exemption is granted pursuant to subsection (3) of this section. Corrections to the DFC report, as noted in WAC **246-310-827**(7) do not require the filing on an exemption.

(3) A provider may request an exemption from subsection (2) of this section in writing by the first working day in March. The exemption request must demonstrate that reasonable efforts were made to timely submit the required data elements in subsection (1)(a) and (b) of this section. An exemption request based on missing data in the DFC report or QIP report should demonstrate the absence of data is not the result of failure to report to medicare. The department has sole discretion to grant these exemptions. The department will review all submitted exemption requests and respond with a decision by the first working day in April.

(4) Within ten working days, providers must report to the department the date that kidney dialysis stations first became operational for the following:

(a) New kidney dialysis facility;

(b) Stations added to an existing kidney dialysis facility; or

(c) Relocated stations of a kidney dialysis facility.

(5) The department will confirm it has received the required data in subsections (1) and (4) of this section as well as any exemption requests in subsection (3) of this section via email within ten working days of receipt.

(6) The department will publish on its website the date that the stations in subsection (4) of this section became operational.

246-310-806 Kidney disease treatment facilities—Concurrent review cycles.

The department will review kidney dialysis facility applications using the concurrent review cycles described in this section, unless the application was submitted as described in subsection (9) of this section. There are four concurrent review cycles each year.

(1) Applicants must submit applications for review according to the following table:

		Application Submission Period			Department Action	Application Review Period		
Concurrent Review Cycle	Letters of Intent Due	Receipt of Initial Application	End of Screening Period	Applicant Response	Beginning of Review	Public Comment Period (includes public hearing if requested)	Rebuttal Period	Exparte Period
Special Circumstances 1	First working day of **April** of each year.	First working day of **May** of each year.	**May 15** or the first working day thereafter.	**June 15** or the first working day thereafter.	**June 22** or the first working day thereafter.	**30-Day** Public comment period (including public hearing). Begins **June 23** or the first working day thereafter.	**7-Day** Rebuttal period. Applicant and affected party response to public comment.	**15-Day** Exparte period. Department evaluation and decision.
Nonspecial Circumstance Cycle 1	First working day of **May** of each year.	First working day of **June** of each year.	Last working day of **June**.	Last working day of **July**.	**August 5** or the first working day thereafter.	**30-Day** Public comment period (including public hearing). Begins **August 6** or the first working day thereafter.	**30-Day** Rebuttal period. Applicant and affected party response to public comment.	**75-Day** Exparte period. Department evaluation and decision.
Special Circumstances 2	First working day of **October** of each year.	First working day of **November** of each year.	**November 15** or the first working day thereafter.	**December 15** or the first working day thereafter.	**December 22** or the first working day thereafter.	**30-Day** Public comment period (including public hearing). Begins **December 23** or the first working day thereafter.	**7-Day** Rebuttal period. Applicant and affected party response to public comment.	**15-Day** Exparte period. Department evaluation and decision.
Nonspecial Circumstances Cycle 2	First working day of **November** of each year.	First working day of **December** of each year.	Last working day of **December**.	Last working day of **January**.	**February 5** or the first working day thereafter.	**30-Day** Public comment period (including public hearing). Begins **February 6** or the first working day thereafter.	**30-Day** Rebuttal period. Applicant and affected party response to public comment.	**75-Day** Exparte period. Department evaluation and decision.

(2) The department should complete a nonspecial circumstance concurrent review cycle within nine months, which begins the first day after letters of intent are due for that particular review cycle. The department should complete the regular review process within six months, which begins the first day after the letters of intent are due for that particular review cycle.

(3) The department will notify applicants fifteen days prior to the scheduled decision date if it is unable to meet the decision deadline on the applications. In that event, the department will establish and commit to a new decision date.

(4) When two or more applications are submitted for the same planning area, the department will first evaluate each application independently for meeting the applicable standards described in WAC **246-310-210**, **246-310-220**, **246-310-230**, and **246-310-240**. If two or more applications independently meet those four standards, the department will apply the superiority criteria in WAC **246-310-827** to determine the superior application under WAC **246-310-240**(1).

(5) An applicant receiving points for the purposes of the superiority criteria under WAC **246-310-827** (3)(e), (f), or (g) may only apply for station need in one planning area per review cycle.

(6) An applicant receiving points for purposes of the superiority criteria under WAC **246-310-827** (3)(e), (f), or (g) must operate the newly awarded stations for a period of time long enough to have a full year of data reporting medicare cost report worksheets and a full year of data reporting the dialysis facility report prior to any future applications.

(7) The department will not accept new nonspecial circumstance applications for a planning area if there are any nonspecial circumstance applications for which the certificate of

need program has not made a decision in that planning area filed under a previous concurrent review cycle. This restriction does not apply if the department has not made a decision on the pending applications within the review timelines of nine months for a concurrent review and six months for a regular review. This restriction also does not apply to special circumstance applications.

(8) The department may convert the review of a nonspecial circumstance application that was initially submitted under a concurrent review cycle to a regular review process if the department determines that the nonspecial circumstance application does not compete with another nonspecial circumstance application.

(9) Pending certificate of need applications. Kidney dialysis facility applications submitted prior to the effective date of these rules will be reviewed and action taken based on the rules that were in effect on the date the applications were received.

~~(10) Written requests by a kidney disease treatment center for additional dialysis stations due to a temporary emergency situation pursuant to WAC 246-310-824(2) are not subject to the concurrent review timelines.~~

FMCNA Comment

FMCNA is supportive of the language included in the Department's proposed rule change presented as WAC 246-310-806(10). Based on review of the full set of the proposed rule changes, FMCNA recommends moving this language to a new section, WAC 246-310-836, that is specific to temporary emergency exemption requests.

246-310-809 One-time exempt isolation station reconciliation.

(1) The department will identify each certificate of need approved kidney dialysis facility and the total number of certificate of need approved stations as of the effective date of these rules.

(2) The department will make a one-time administrative station adjustment to each kidney dialysis facility to add one station as an approved exempt isolation station for those facilities that were approved prior to the effective date of these rules.

(3) The department will notify each kidney dialysis facility of its adjusted certificate of need approved station count.

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

A kidney dialysis facility that provides hemodialysis or peritoneal dialysis, training, or backup must meet the following standards in addition to applicable review criteria in WAC **246-310-210**, **246-310-220**, **246-310-230**, and **246-310-240**.

(1) Applications for new stations may only address projected station need in the planning area in which the facility is to be located.

(a) If there is no existing facility in an adjacent planning area, the application may also address the projected station need in that planning area.

(b) Station need projections must be calculated separately for each planning area within the application.

(2) Data used to project station need must be the most recent five-year resident end-of-year in-center patient data available from the Northwest Renal Network as of the letter of intent submission date, concluding with the base year at the time of application.

(3) Projected station need must be based on 4.8 resident in-center patients per station (4.8 planning area) for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, Wahkiakum, and Whitman counties. The projected station need for these exception planning areas must be based on 3.2 resident in-center patients per station (3.2 planning area).

(4) The number of dialysis stations projected as needed in a planning area will be determined by using the following methodology:

(a) Determine the type of regression analysis to be used to project resident in-center station need by calculating the annual growth rate in the planning area using the end-of-year number of resident in-center patients for each of the previous six consecutive years, concluding with the base year.

(i) If the planning area has experienced less than six percent growth in any of the previous five annual changes calculations, use linear regression to project station need; or

(ii) If the planning area has experienced six percent or greater growth in each of the previous five annual changes, use nonlinear (exponential) regression to project station need.

(b) Project the number of resident in-center patients in the projection year using the regression type determined in (a) of this subsection. When performing the regression analysis use the previous five consecutive years of end-of-year data concluding with the base year. For example, if the base year is 2015, use end-of-year data for 2011 through 2015 to perform the regression analysis.

(c) Determine the number of dialysis stations needed to serve resident in-center patients in the planning area in the projection year by dividing the result of (b) of this subsection by the appropriate resident in-center patient per station number from subsection (3) of this section. In order to assure access, fractional numbers are rounded up to the nearest whole number. For example, 5.1 would be rounded to 6.0. Rounding to a whole number is only allowed for determining the number of stations needed.

(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) and dialysis stations added

during a temporary emergency situation defined in ~~WAC 246-310-824(2)~~WAC 246-310-836. 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.

FMCNA Comment
See proposed WAC 246-310-836, a new section added at the end of the kidney dialysis rules that is specific to temporary emergency exemptions. The new WAC 246-310-836 section is intended to replace the Department's originally proposed WAC 246-310-824(2) and that is why the WAC reference above is changed.

(5) Before the department approves new in-center kidney dialysis stations in a 4.8 planning area, all certificate of need counted stations at each facility in the planning area must be operating at 4.5 in-center patients per station. However, when a planning area has one or more facilities with stations not meeting the in-center patients per stations standard, the department will consider the 4.5 in-center patients per station standard met for those facilities when:

(a) All stations for a facility have been in operation for at least three years, excluding temporary emergency stations defined in WAC 246-310-836; or

FMCNA Comment
The rules should clearly establish that temporary emergency stations are not considered in the Department's assessment of a facility's conformance to WAC 246-310-812(5)(a).

(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~~.~~; or

(c) A facility was affected by a temporary emergency, as defined in WAC 246-310-836(4)(a), 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.

FMCNA Comment
See proposed WAC 246-310-836(4)(a) for additional details for how to determine whether a facility should be considered affected by a temporary emergency.

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 WAC 246-310-812(5)(a)-(b) or (6)(a)-(b) are met. However, utilization rates may be distorted if a facility has expanded capacity under the new temporary exemption law or is otherwise impacted by an emergency situation. For example, a facility may experience a higher patient census if operating temporary emergency stations. Another facility may experience a lower patient census if it is impacted by a natural disaster, physical plant issues, etc. that causes it to cease operations partially or entirely for an interim period.

Because a facility's patient-per-station occupancy can be distorted, 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 affected by a temporary emergency during the time period of the applicable ESRD modality report for the review cycle.

The timing described in the proposed rule change (i.e. "… in the most recent quarterly modality report from the ESRD Network as of the letter of intent submission date") is necessary to tie this proposal to the applicable ESRD modality report for the review cycle used when the Department evaluates a facility's conformance to WAC 246-310-812(5)-(6).

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.

(6) Before the department approves new in-center kidney dialysis stations in a 3.2 planning area, all certificate of need counted stations at each facility in the planning area must be operating at or above 3.2 in-center patients per station. If the certificate of need approval is contested, the eight months would start from the date of the final department or judicial order. However, when a planning area has facilities with stations not meeting the in-center patients per station standard, the department will consider the 3.2 in-center patients per station standard met for those facilities when:

(a) All stations for a facility have been in operation for at least three years, excluding temporary emergency stations defined in WAC 246-310-836; or

FMCNA Comment

See comment for WAC 246-310-812(5)(a).

(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. However, the department, at its sole discretion, may approve a one-time modification of the timeline for the purposes of this subsection upon submission of documentation that the applicant was prevented from meeting the initial timeline due to circumstances beyond its control.; or

(c) A facility was affected by a temporary emergency, as defined in WAC 246-310-836(4)(a), 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.

FMCNA Comment
See comment for WAC 246-310-812(5)(c).

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.

(7) When there are relocated stations within a planning area pursuant to WAC **246-310-830**(3) and data is not available for the relocated stations, the department will use the station use rate from the previous location as reported on the last quarterly modality report from Northwest Renal Network.

(8) If a provider, including any affiliates, submits multiple applications for projected need in a planning area, the department will use the following process:

(a) Each application will be scored as an individual application to determine superiority.

(b) The sum of the stations requested in the applications cannot exceed the projected need at the time of applications in the planning area.

246-310-815 Kidney disease treatment facilities—Financial feasibility.

(1) The kidney dialysis facility must demonstrate positive net income by the third full year of operation.

(a) The calculation of net income is subtraction of all operating and nonoperating expenses, including appropriate allocated and overhead expenses, amortization and depreciation of capital expenditures from total revenue generated by the kidney dialysis facility.

(b) Existing facilities. Revenue and expense projections for existing facilities must be based on that facility's current payor mix and current expenses.

(c) New facilities.

(i) Revenue projections must be based on the net revenue per treatment of the applicant's three closest dialysis facilities.

(ii) Known expenses must be used in the pro forma income statement. Known expenses may include, but are not limited to, rent, medical director agreement, and other types of contracted services.

(iii) All other expenses not known must be based on the applicant's three closest dialysis facilities.

(iv) If an applicant has no experience operating kidney dialysis facilities, the department will use its experience in determining the reasonableness of the pro forma financial statements provided in the application.

(v) If an applicant has one or two kidney dialysis facilities, revenue projections and unknown expenses must be based on the applicant's operational facilities.

(2) An applicant proposing to construct finished treatment floor area square footage that exceeds the maximum treatment floor area square footage defined in WAC **246-310-800**(11) will be determined to have an unreasonable impact on costs and charges and the application will be denied. This does not preclude an applicant from constructing shelled space.

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

(1) The department will approve one or two additional special circumstance stations for an existing kidney dialysis facility (facility) if it meets the following criteria, regardless of whether the need methodology in WAC **246-310-812** projects a need for additional stations in the planning area:

(a) For 4.8 planning areas, the facility has operated at or above an average of 5.0 patients per station for the most recent six consecutive month period preceding the letter of intent submission date for which data is available. Data used to determine patients per station must be obtained from the Northwest Renal Network; or

(b) For 3.2 planning areas, the facility has operated at or above an average of 3.5 patients per station for the most recent six consecutive month period preceding the letter of intent submission date for which data is available. Data used to determine patients per station must be obtained from the Northwest Renal Network; and

(c) The facility can accommodate one or two additional stations within its existing building, which may include shelled space. If renovation is needed to accommodate the additional station(s), renovation must be within the existing building.

(2) The department may approve special circumstance station expansions even if other kidney dialysis facilities not owned or affiliated with the applicant in the planning area are below the minimum patients per station operating thresholds set by WAC **246-310-812** (5) or (6).

(3) A facility approved for two special circumstance stations under subsection (1) of this section is not eligible for further special circumstance expansions under this subsection until the department awards additional nonspecial circumstances kidney dialysis stations in the planning area.

(4) As of the effective date of these rules, a facility that has relocated all or part of its stations may not request a special circumstance one- or two-station expansion until three years have lapsed from the date the stations become operational. The three-year prohibition applies to any new kidney dialysis facility or facilities whose station count is changed by the relocation of stations. The three-year prohibition will be retrospectively applied only to kidney dialysis facilities that were approved for partial or complete relocation after January 1, 2015.

(5) For 4.8 planning areas, a facility is ineligible for a special circumstance one- or two-station expansion if the owner or affiliate has approved certificate of need stations in the planning area that have operated below an average of 4.5 patients per station for the most recent six consecutive month period preceding the letter of intent submission date. Data used to calculate patients per station must be obtained from the Northwest Renal Network.

(6) For 3.2 planning areas, a facility is ineligible for a special circumstance one- or two-station expansion if the owner or affiliate has approved certificate of need stations in the planning area that have operated below an average of 3.2 patients per station for the most recent six consecutive month period preceding the letter of intent submission date. Data used to calculate patients per station must be obtained from the Northwest Renal Network.

(7) For 4.8 planning areas, a special circumstance one- or two-station expansion will not be approved if, with the requested new station(s), the applicant's kidney dialysis facility would

fall below a calculated 4.5 patients per station. Data used to make this calculation is the average patients per station from subsection (1)(a) of this section.

(8) For 3.2 planning areas, a special circumstance one- or two-station expansion will not be approved if, with the requested new stations(s), the applicant's kidney dialysis facility would fall below a calculated 3.0 patient per station. Data used to make this calculation is the average patients per station from subsection (1)(b) of this section.

(9) If a provider operates one or more kidney dialysis facilities within a planning area and applies for a special circumstance one- or two-station expansion in the planning area the department will not accept a letter of intent from that provider for additional stations to meet projected planning area need in the next nonspecial circumstance concurrent review cycle.

(10) Station(s) approved under this section must be operational within six months of approval, otherwise the approval is revoked.

(11) The department will provide a special circumstance one- or two-station expansion application form that incorporates the criteria for certificate of need approval. The application will not be approved unless the criteria are met. Special circumstances applications are evaluated independently of one another and accordingly without reference to the superiority criteria set forth in WAC **246-310-827**. Therefore, multiple special circumstances applications may be approved in the same planning area during the same concurrent review cycle.

(12) Applicants must submit special circumstance one- or two-station expansion applications according to the schedule set forth in WAC **246-310-806**(1).

(13) Special circumstance station applications will be treated as approved and will reduce net station need in the planning area when no nonspecial circumstance applications decisions are pending within the planning area. Special circumstance application approvals will not result in a reduction of net station need in the planning area when nonspecial circumstance application approvals decisions are pending within the planning area.

(14) The department will review special circumstance requests with the following considerations related to temporary emergency stations defined in WAC 246-310-836:

(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).

FMCNA Comment

Rationale for proposed (14)(a): the rules should clearly state that temporary emergency stations are excluded from the special circumstance need methodology.

Rationale for proposed (14)(b): a facility's patient census and patient-per-station occupancy will be distorted if it is operating additional temporary emergency stations. While most facilities should be excluded from applying for special circumstance requests in the next applicable review cycle, those facilities operating temporary emergency stations due to staffing shortages should still be allowed to apply for special circumstance. 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. If a facility was operating at high occupancy before requesting temporary exemption stations [for staffing emergencies], then it should be allowed to eligible to apply for a special circumstance request in the next applicable review cycle.

246-310-821 Kidney disease treatment facilities—Standards for planning areas without an existing facility.

(1) Columbia, Ferry, Garfield, Klickitat, Lincoln, Pend Oreille, San Juan, Skamania, Stevens, Wahkiakum, and Whitman counties do not have an existing kidney dialysis facility as of the effective date of these rules. The department will award the first project proposing to establish a facility in each of these planning areas as follows:

(a) A minimum of four stations, provided the project meets applicable review criteria and standards; and

(b) The facility must be projected to operate at 3.2 in-center patients per station by the third full year of operation. For purposes of this subsection, the applicant may supplement data obtained from the Northwest Renal Network with other documented demographic and utilization data to demonstrate station need.

(2) Once a county no longer qualifies under subsection (1) of this section, the county remains a 3.2 in-center patient per station county. As of the effective date of these rules, Adams, Douglas, Jefferson, Kittitas, Okanogan, Pacific, and Stevens counties are also identified as 3.2 in-center patient per station counties.

246-310-824 Kidney disease treatment centers—Exceptions.

The department will not approve new stations in a planning area if the projections in WAC **246-310-812**(4) show no net need, and will not approve more than the number of stations projected as needed unless:

(1) The proposed project qualifies under WAC **246-310-818** for special circumstances one- or two-station expansions; or

~~(2) A kidney disease treatment center is granted an exemption to exceed its authorized number of dialysis stations during a temporary emergency situation, as defined by RCW 70.38.XXX.~~

~~(a) In addition to the temporary emergency situations identified in RCW 70.38. XXX(2), the following are defined as temporary emergency situations:~~

~~(i) Any state or federal emergency declaration issued by a state or federal entity that has a direct impact on availability, operations, or patient access to kidney dialysis services in Washington state.~~

~~(b) For purposes of RCW 70.38. XXX(2)(d), "reconfiguration" means the temporary transfer of exempt stations from a facility unable to provide treatment due to staffing shortages to an adequately staffed receiving facility.~~

~~(c) In order to be granted an temporary emergency situation exemption, a kidney disease treatment center must make a written request to the department consistent with RCW 70.38. XXX(3). In addition to the information required in RCW 70.38. XXX(3), the following information is required:~~

~~(i) A specific description of the actions the kidney disease treatment center will take to address the temporary emergency situation.~~

~~(ii) A description of any patient harm that occurred due to the temporary emergency situation.~~

~~(d) A kidney disease treatment center who seeks to exceed its authorized number of dialysis stations due to a temporary emergency situation must submit a written request to the department consistent with WAC 246-310-824(2)(c).~~

~~(e) A kidney disease treatment center may submit a temporary emergency situation exemption request at any time and is not subject to the concurrent review cycles for kidney disease treatment centers in WAC 246-310-806.~~

FMCNA Comment

See proposed WAC 246-310-836, a new section added at the end of the kidney dialysis rules that is specific to temporary emergency exemptions.

(~~3~~2) All other applicable review criteria and standards have been met; and

(~~4~~3) One or more of the following have been met:

(a) The department finds the additional stations are needed to be located reasonably close to the people they serve; or

(b) Existing dialysis stations in the kidney dialysis facility requesting the exception are operating at 5.5 patients for a 4.8 planning area or, 3.7 patients per station for the 3.2 planning areas. 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; or

(c) The applicant documents a significant change in ESRD treatment practice has occurred, affecting dialysis station use in the planning area; and

(~~5~~4) The department finds that exceptional circumstances exist within the planning area and explains the approval of additional stations in writing.

246-310-827 Kidney disease treatment facilities—Superiority criteria.

For purposes of determining which of the competing applications should be approved, the criteria in this section will be used as the only means for comparing two or more applications to each other. No other criteria or measures will be used in comparing two or more applications to each other under any of the applicable subcriteria within WAC **246-310-210**, **246-310-220**, **246-310-230** or **246-310-240**.

(1) An application will be denied if it fails to meet any criteria under WAC **246-310-210**, **246-310-220**, **246-310-230**, or **246-310-240** (2) or (3).

(2) An application will be denied if the applicant has one or more kidney dialysis facilities in the planning area not meeting the 4.5 or 3.2 in-center patients per station standards required in WAC **246-310-812** (5) or (6) as of the most recent quarterly report from the Northwest Renal Network as of the date of the letter of intent.

(3) When available, Washington facilities must be used as comparables, as follows:

(a) For existing kidney dialysis facilities proposing to expand, use data for the existing facility plus the next two closest Washington facilities as comparables owned by or affiliated with the applicant as measured by a straight line. Straight lines will be calculated using "Google Maps" or equivalent mapping software (mileage calculated out to two decimal points, no rounding).

(b) For new kidney dialysis facilities, use data for the next three closest facilities as comparables owned by or affiliated with the applicant as measured by a straight line from the proposed new kidney dialysis facility location. Straight lines will be calculated using "Google Maps" or equivalent mapping software (mileage calculated out to two decimal points, no rounding).

(c) The number of applications per concurrent review cycle that rely on the same three comparables is limited to two.

(d) If complete medicare data is not available for any of the kidney dialysis facilities and a facility has been granted a department exemption in WAC **246-310-803**(3), then that facility will not be used as a comparable and the next closest facility should be used as a comparable.

(e) If the applicant currently does not own or is not affiliated with any kidney dialysis facility, the department will assign the following points:

(i) The median quintile points for those superiority measures using quintiles (excluding net revenue per treatment);

(ii) Two points for standardized mortality ratio (SMR);

(iii) Two points for standardized hospitalization ratio (SHR); and

(iv) Any remaining points for other measures will be based on the representations made in the application.

(f) If the applicant owns or is affiliated with one existing kidney dialysis facility in total, the department will assign the facility's actual points as follows:

(i) The actual quintile points for those superiority measures using quintiles;

(ii) The actual points for SMR;

(iii) The actual points for SHR; and

(iv) Any remaining points for other measures will be based on the representations made in the application.

(g) If the applicant owns or is affiliated with two existing kidney dialysis facilities in total, the department will average the facility's scores as follows:

(i) The average quintile points for those superiority measures using quintiles;

(ii) The average points for SMR;

(iii) The average points for SHR; and

(iv) The average of the remaining points for other measures will be based on the representations made in the applications.

(4) The following table identifies the data measures and the data sources:

Data Item	Source
Home peritoneal dialysis and home hemodialysis training (Yes or No)	DFC report
Shift beginning after 5:00 p.m.? (Yes or No)	DFC report
Nursing home residents percentage (quintile)	Dialysis facility report (DFR)
Average number of comorbidities claimed (quintile)	Dialysis facility report (DFR)
Standardized mortality ratio performance (SMR)(better than expected, as expected, worse than expected)	DFC report - 4 year
Standardized hospitalization ratio performance (SHR) (better than expected, as expected, worse than expected)	DFC report - 1 year
Medicare total performance score (quintile)	QIP report
Net revenue per treatment (quintile)	Department calculation from medicare cost report. Divide total revenue by total treatments.

(5) The department will obtain the medicare QIP total performance scores (QIP Report) and the kidney dialysis facility compare reports (DFC Report) from the medicare website on the first working day in February.

(6) The department will determine the quintile scores and nonquintile scores. The department will calculate the quintile scores using the following process for each quintile measure:

(a) For all kidney dialysis facilities for which data is available, sort the facilities from most favorable to least favorable according to the identified data.

(b) Use the percent rank formula using Excel to create the percentile ranking for each kidney dialysis facility in the data set. The array used in the formula is the data set of available facility data identified for that measure.

(c) Assign quintile and nonquintile scores using the following methods:

(i) Quintile measures. For nursing home resident percentage, number of comorbidities, and QIP total performance score measures, the department will determine the quintile scores using the following process:

(A) Dialysis facilities with a percentile ranking of eighty percent or higher get five points.

(B) Dialysis facilities with a percentile ranking less than eighty percent and greater than or equal to sixty percent get four points.

(C) Dialysis facilities with a percentile ranking less than sixty percent and greater than or equal to forty percent get three points.

(D) Dialysis facilities with a percentile ranking less than forty percent and greater than or equal to twenty percent get two points.

(E) Dialysis facilities with a percentile ranking below twenty percent get one point.

(ii) Quintile measure. For the net revenue per treatment measure, the department will determine the quintile scores using the following process:

(A) Dialysis facilities with a percentile ranking of eighty percent or higher get one point.

(B) Dialysis facilities with a percentile ranking less than eighty percent and greater than or equal to sixty percent get two points.

(C) Dialysis facilities with a percentile ranking less than sixty percent and greater than or equal to forty percent get three points.

(D) Dialysis facilities with a percentile ranking less than forty percent and greater than or equal to twenty percent get four points.

(E) Dialysis facilities with a percentile ranking below twenty percent get five points.

(F) Hospitals that do not have a cost report may submit net revenue per treatment actuals from the previous year. Hospitals must also submit a signed attestation stating the net revenue per treatment data is accurate.

(iii) Nonquintile measures. The department will determine the nonquintile scores using the following process:

(A) Dialysis facilities that offer training services are given one point.

(B) Dialysis facilities that offer a shift that begins after 5 p.m. are given one point.

(C) The department will determine SMR points for dialysis facilities as follows:

(I) "Better than expected" get four points.

(II) "As expected" get two points.

(III) "Worse than expected" get 0 points.

(D) The department will determine SHR points for dialysis facilities as follows:

(I) "Better than expected" get four points.

(II) "As expected" get two points.

(III) "Worse than expected" get 0 points.

(E) The department will assign two points for an "as expected" score for dialysis facilities missing only SMR data from the DFC report, provided the facility was granted an exception under WAC **246-310-803**(3).

(7) The department will publish the data set including resulting scores and quintiles for all kidney dialysis facilities for review no later than March 15th or the first working day thereafter. The data set, including resulting scores and quintiles, will remain open for review and any person may propose the correction of data to the department for seven calendar days. Correction of data may be proposed as follows:

(a) Training services (HPD and HHD): The department will accept a copy of a medicare certification for training services (HPD and HHD) as evidence that a kidney dialysis facility provides these services, regardless of what is represented in the DFC report.

(b) Data related to a shift beginning after 5 p.m.: The department will accept an attestation that a facility either operates a shift beginning after 5 p.m. or will operate that shift if there is a need, regardless of what is represented in the DFC report.

(c) The department will publish the final data set, including resulting scores and quintiles, no later than the first working day in April.

(8) The department will do the following analysis in order to determine the superior application:

(a) Create the comparable kidney dialysis facility set for each application per subsection (3) of this section.

(b) Determine the individual measure scores for each application by taking the simple average of the comparable scores for each measure.

(c) Determine the total score in the following manner according to the table below:

Data Items:	Calculation of Points	Score
Home training	The average score of comparable facilities rounded up to two decimal places.	
Shift beginning after 5 p.m.	The average score of comparable facilities rounded up to two decimal places.	
Nursing home residents	Average quintile score of comparable facilities rounded up to two decimal places.	
Average number of comorbid conditions	Average quintile score of comparable facilities multiplied by 1.25 and rounded up to two decimal places.	
Standardized mortality ratio	Average score of comparable facilities rounded up to two decimal places.	
Standardized hospitalization ratio	Average score of comparable facilities rounded up to two decimal places.	
QIP total performance score	Average quintile score of comparable facilities multiplied by 2.0 and rounded up to two decimal places.	
Net revenue per treatment	Average quintile score of comparable facilities rounded down to two decimal places.	
Total score	Sum each of these individual average scores to arrive at total score.	

(9) The application with the highest total score will be the superior alternative for the purpose of meeting WAC **246-310-240**(1).

(10) After applying the superiority criterion in this section, if applications are tied, the department will use the following process to determine the superior alternative:

(a) An applicant that was assigned points under subsection (3)(e) of this section in the superiority analysis will be considered the superior alternative; if no applicant was assigned points under subsection (3)(e) of this section, apply (b) of this subsection:

(b) The applicant with the highest average QIP total performance score will be considered the superior alternative;

(c) If applications have the same average QIP total performance score, the applicant with the lowest average net revenue per treatment will be considered the superior alternative.

246-310-830 Kidney disease treatment facilities—Relocation of facilities.

(1) When an existing facility proposes to relocate any of its stations to another planning area, a new health care facility is considered to be established under WAC **246-310-020** (1)(a).

(2) When an existing kidney dialysis facility proposes to relocate a portion but not all of its stations within the same planning area, a new health care facility is considered to be established under WAC **246-310-020** (1)(a).

(3) When an existing kidney dialysis facility proposes to relocate a portion but not all of its stations to an existing facility, it will be considered a station addition under WAC **246-310-020** (1)(e).

(4) When an entire existing kidney dialysis facility proposes to relocate all of its stations within the same planning area, a new health care facility is not considered to be established under WAC **246-310-020** (1)(a) if:

(a) The existing kidney dialysis facility ceases operation after the relocation;

(b) No new stations are added to the replacement kidney dialysis facility. The maximum treatment floor area square footage as defined in WAC **246-310-800** (11)(a) is limited to the number of certificate of need stations that were approved at the existing facility;

(c) There is no break in service between the closure of the existing kidney dialysis facility and the operation of the replacement facility;

(d) The existing facility has been in operation for at least five years at its present location; and

(e) The existing kidney dialysis facility has not been purchased, sold, or leased within the past five years.

(5) Station use rates at new facilities created by the total relocation of an existing facility or the partial relocation of an existing facility should not be a barrier to the addition of new stations projected as needed for the planning area. In 4.8 planning areas, the station use rate will be counted as 4.5 in-center patients per station. If the department has had to count the station use at 4.5 under the need methodology described in WAC **246-310-812**(5), the facility may not request additional stations at the new facility for three years from the date the stations become operational or the facility meets the 4.5 station use standard, whichever comes first. Data used to make this determination will be the most recent Northwest Renal Network quarterly modality report available as of the letter of intent submission date.

(6) Station use rates at new facilities created by the total relocation of an existing facility or the partial relocation of an existing facility should not be a barrier to the addition of new stations projected as needed for the planning area. In 3.2 planning areas, the station use rate will be counted as 3.2 in-center patients per station. If the department has had to count the station use at 3.2 under the need methodology described in WAC **246-310-812**(6), the facility may not request additional stations at the new facility for three years from the date the stations become operational or the facility meets the 3.2 station use standard, whichever comes first. Data used to make this determination will be the most recent Northwest Renal Network quarterly modality report available as of the letter of intent submission date.

246-310-833 One-time state border kidney dialysis facility station relocation.

(1) When an existing owner-operator of a Washington state kidney dialysis facility is also the owner-operator of a kidney dialysis facility in a contiguous Idaho or Oregon county, the department will not consider a facility that combines the Washington facility and the out-of-state facility to be a new health care facility under WAC **246-310-020**(1) provided all of the following criteria are satisfied:

(a) The Washington state kidney dialysis facility is located in Asotin, Benton, Clark, Columbia, Cowlitz, Garfield, Klickitat, Pend Oreille, Skamania, Wahkiakum, Walla Walla, or Whitman counties;

(b) The kidney dialysis facility is the sole provider of dialysis services in the Washington state county;

(c) The kidney dialysis facility is the sole provider of dialysis services in the contiguous Idaho or Oregon county;

(d) The replacement kidney dialysis facility will be located in the same county or planning area as the current Washington state facility;

(e) Both existing kidney dialysis facilities cease operation;

(f) There is no break in service between the closure of the existing kidney dialysis facilities and the operation of the replacement facility;

(g) There has been no change in ownership of either the Washington kidney dialysis facility or out-of-state kidney dialysis facility for at least five years prior to applying for the exemption under this section;

(h) Each existing kidney dialysis facility has been operated by the current provider for a minimum of five years prior to applying for the exemption under this section;

(i) Each existing kidney dialysis facility has been operating at its current location for a minimum of five years prior to applying for the exemption under this section;

(j) The department has not granted a previous exemption under the provisions of this section; and

(k) The number of stations at the replacement kidney dialysis facility does not exceed the total of:

(i) All stations from the Washington state kidney dialysis facility; and

(ii) Using the 4.8 patients per station standard, the stations necessary for the number of patients receiving dialysis at the out-of-state kidney dialysis facility as reported on the most recent Northwest Renal Network quarterly modality report.

(2) Once a Washington state provider has requested and received its one-time exemption under the provisions of this section, the kidney dialysis facility's "resident in-center patient" will have the same meaning as all patients at the facility.

246-310-836 Kidney disease treatment facilities—Temporary Emergency Station Exemptions

The department may grant ~~A~~a kidney disease treatment center ~~is granted~~ an exemption to exceed its authorized number of dialysis stations during a temporary emergency situation, as defined by RCW 70.38. ~~XXX~~280.

(~~a~~1) In addition to the temporary emergency situations identified in RCW 70.38. ~~XXX~~280(2), the following are defined as temporary emergency situations:

(~~i~~a) Any state or federal emergency declaration issued by a state or federal entity that has a direct impact on availability, operations, or patient access to kidney dialysis services in Washington state;

(b) 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; and

(c) Severe disruption to transportation infrastructure like roads, bridges, or public transit that severely limits patient access to facilities.

FMCNA Comment
FMCNA recommends adding (b) and (c) proposed above to ensure other emergency situations (e.g. disease outbreaks, severe infrastructure disruptions) are recognized as qualifying emergency situations.

(~~b~~2) For purposes of RCW 70.38.~~XXX~~280(2)(d), "reconfiguration" means the addition of dialysis stations to facilitate the delivery of dialysis services as long as the facility does not exceed the number of patients served at the time of the exemption request. ~~temporary transfer of exempt stations from a facility unable to provide treatment due to staffing shortages to an adequately staffed receiving facility.~~

FMCNA Comment
No transfer of stations from one facility to another is contemplated in RCW 70.38.280(2)(d). The additional temporary emergency station due to a staffing emergency is to allow greater efficiency such as shift optimization that may not be feasible with the current CN-approved station count.

This subsection should also reiterate the maximum patient count required under RCW 70.38.280(2)(d).

(3) In order to be granted ~~an~~ a temporary emergency situation exemption, a kidney disease treatment center must make a written request to the department consistent with RCW

70.38.~~XXX~~280(3). Written requests may be sent via email. In addition to the information required in RCW 70.38.~~XXX~~280(3), the following information is required:

FMCNA Comment
RCW 70.38.280(3) allows written requests to be sent via email. This should be further codified in the WAC.

(~~i~~a) A specific description of the actions the kidney disease treatment center will take to address the temporary emergency situation.

(~~ii~~b) A description of any patient harm that ~~occurred~~has or is reasonably expected to occur due to the temporary emergency situation.

FMCNA Comment
A description of actual patient harm should not be required to grant a temporary exemption if patient harm is reasonably expected to occur. While some emergency situations will have direct patient harms (e.g. natural disasters), there may be other emergent events (e.g. certain physical plant issues) that requires immediate attention but may not have yet caused patient harm.

~~(d) A kidney disease treatment center who seeks to exceed its authorized number of dialysis stations due to a temporary emergency situation must submit a written request to the department consistent with WAC 246-310-824(2)(c).~~

FMCNA Comment
This language duplicates subsection (c).

(4) The department will make a decision within three working days of receipt of a facility's written request for temporary emergency stations, as described in subsection (3).

(a) In the department's decision letter, it must identify the list of facilities it finds to be affected by the temporary emergency. Multiple facilities may be listed as affected facilities even if not all facilities are granted additional temporary stations. For example, if a facility (Facility A) is impacted by a natural emergency and another facility (Facility B) requests additional temporary emergency stations to serve Facility A's patients, then both Facility A and Facility B are considered affected by a temporary emergency situation.

FMCNA Comment
See proposed WAC 246-310-812(5)(c) and (6)(c) for how this list of affected facilities defined in WAC 246-310-836(4)(a) is used in the proposed changes to the nonspecial circumstance need methodology.

(~~e~~5) A kidney disease treatment center may submit a temporary emergency situation exemption request at any time and is not subject to the concurrent review cycles for kidney disease treatment centers in WAC 246-310-806.

(6) A kidney disease treatment center's certificate of need shall remain in full effect even if the facility is required to suspend operations, in part or in its entirety, due to circumstances that qualify as a temporary emergency situation. The facility may restore its full authorized operations once the temporary emergency has ended without having to reapply for certificate of need approval.

FMCNA Comment

The rules should safeguard a facility's certificate of need, so it is not jeopardized if it suspends operations due to a temporary emergency. Current rules have no exception for those types of situations, and as a result, such a suspension could result in partial or full revocation of the facility's certificate of need.

Ensuring facilities can restore capacity after a temporary emergency-related closure will support continuity of care without unnecessary regulatory delays.

(7) The department will publish on its website all written requests and department decisions related to kidney disease treatment center requests for additional dialysis stations due to a temporary emergency situation. The information will also include a list of affected facilities. This information will be published on the department's website within five working days of receipt of the written requests and within five working days of the department's decision.

FMCNA Comment

Requiring timely posting of exemption requests and decisions as well as information related to affected facilities 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, and is approved, for a temporary emergency exemption.

Clean Copy of Proposed WAC 246-310-836

246-310-836 Kidney disease treatment facilities—Temporary Emergency Station Exemptions

The department may grant a kidney disease treatment center an exemption to exceed its authorized number of dialysis stations during a temporary emergency situation, as defined by RCW 70.38.280.

(1) In addition to the temporary emergency situations identified in RCW 70.38.280(2), the following are defined as temporary emergency situations:

(a) Any state or federal emergency declaration issued by a state or federal entity that has a direct impact on availability, operations, or patient access to kidney dialysis services in Washington state;

(b) 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; and

(c) Severe disruption to transportation infrastructure like roads, bridges, or public transit that severely limits patient access to facilities.

(2) For purposes of RCW 70.38.280(2)(d), "reconfiguration" means the addition of dialysis stations to facilitate the delivery of dialysis services as long as the facility does not exceed the number of patients served at the time of the exemption request.

(3) In order to be granted a temporary emergency situation exemption, a kidney disease treatment center must make a written request to the department consistent with RCW 70.38.280(3). Written requests may be sent via email. In addition to the information required in RCW 70.38.280(3), the following information is required:

(a) A specific description of the actions the kidney disease treatment center will take to address the temporary emergency situation.

(b) A description of any patient harm that has or is reasonably expected to occur due to the temporary emergency situation.

(4) The department will make a decision within three working days of receipt of a facility's written request for temporary emergency stations, as described in subsection (3).

(a) In the department's decision letter, it must identify the list of facilities it finds to be affected by the temporary emergency. Multiple facilities may be listed as affected facilities even if not all facilities are granted additional temporary stations. For example, if a facility (Facility A) is impacted by a natural emergency and another facility (Facility B) requests additional temporary emergency stations to serve Facility A's patients, then both Facility A and Facility B are considered affected by a temporary emergency situation.

(5) A kidney disease treatment center may submit a temporary emergency situation exemption request at any time and is not subject to the concurrent review cycles for kidney disease treatment centers in WAC 246-310-806.

(6) A kidney disease treatment center's certificate of need shall remain in full effect even if the facility is required to suspend operations, in part or in its entirety, due to circumstances that qualify as a temporary emergency situation. The facility may restore its full authorized

operations once the temporary emergency has ended without having to reapply for certificate of need approval.

(7) The department will publish on its website all written requests and department decisions related to kidney disease treatment center requests for additional dialysis stations due to a temporary emergency situation. The information will also include a list of affected facilities. This information will be published on the department's website within five working days of receipt of the written requests and within five working days of the department's decision.