



PROPOSED RULE MAKING

CR-102 (July 2022) (Implements RCW 34.05.320)

Do NOT use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: April 30, 2024

TIME: 2:15 PM

WSR 24-10-089

Agency: Department of Health

Original Notice

Supplemental Notice to WSR

Continuance of WSR

Preproposal Statement of Inquiry was filed as WSR 23-16-038; or

Expedited Rule Making--Proposed notice was filed as WSR ____; or

Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or

Proposal is exempt under RCW ____.

Title of rule and other identifying information: Kidney disease treatment center temporary emergency exemptions. The Department of Health (department) is proposing a new section, WAC 246-310-825 Kidney disease treatment centers—Temporary emergency situation exemption, and amending existing kidney disease treatment center rules, WAC 246-310-800 through 246-310-833, to implement Substitute Senate Bill (SSB) 5569 (chapter 48, Laws of 2023), codified at RCW 70.38.280.

The department is also proposing amendments to address impacts to the need methodology based upon new temporary emergency situation exemption, as well as clean-up language to ensure consistency in kidney disease treatment center rules.

Hearing location(s):

Department of Health

Date:

Time:

Location: (be specific)

Comment:

June 5, 2024

10:00 a.m.

In-person location:
Department of Health
111 Israel Road SE
Town Center 2, Rm 166 & 167
Tumwater, WA 98501

Virtual:
Register in advance for this webinar:
https://us02web.zoom.us/webinar/register/WN_qpIFFCvySJCrKff7OVk8lg

After registering, you will receive a confirmation email containing information about joining the webinar.

The rule hearing will be hybrid. Individuals may attend either virtually or in-person.

Date of intended adoption: July 1, 2024 Note: This is NOT the effective date)

Submit written comments to:

Name: Ross Valore

Address: PO Box 47852, Olympia, WA 98504-7852

Email: <https://fortress.wa.gov/doh/policyreview/>

Fax: none

Assistance for persons with disabilities:

Contact: Ross Valore

Phone: 564-999-1060

Fax: None

TTY: 711

Other:
By (date): June 5, 2024

Email: cnrulemaking@doh.wa.gov
Other:
By (date): May 29, 2024

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The proposed rule creates two new exemptions for kidney disease treatment centers experiencing a “temporary emergency situation.” The temporary emergency situation exemption allows a kidney disease treatment center to exceed its authorized number of dialysis stations during a temporary emergency situation upon approval by the department. The rule is intended to ensure patients needing dialysis services are able to receive services during an emergency situation and provides flexibility to dialysis centers to exceed their number of approved stations to provide services.

The proposed rules add a new section, WAC 246-310-825, which addresses requirements and the process to obtain a temporary emergency situation exemption. In addition, the proposed new section, WAC 246-310-825, defines “staffing shortage” and “reconfiguration,” and specifies what information must be submitted to the department when applying for a temporary emergency situation exemption. Finally, the department amended existing kidney disease treatment center rules, WACs 246-310-800 through 246-310-833, to address impacts to the need methodology and review requirements for kidney disease treatment centers due to creation of temporary emergency situation exemption.

Reasons supporting proposal: The proposed rule is needed to allow flexibility for kidney disease treatment centers to ensure dialysis patients are able to receive needed healthcare services during a temporary emergency situation. Under current rules, a kidney disease treatment center is not able to exceed its authorized number of dialysis stations. The proposed rule allows for kidney disease treatment centers not impacted by a temporary emergency situation to exceed their authorized number of dialysis stations if they are assuming patients from impacted kidney disease treatment centers or to adjust shifts so that more patients can be treated.

Statutory authority for adoption: RCW 70.38.135 and SSB 5569 (chapter 48, Laws of 2023), codified at RCW 70.38.280

Statute being implemented: RCW 70.38.280

Is rule necessary because of a:

| | | |
|-------------------------|------------------------------|--|
| Federal Law? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| Federal Court Decision? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| State Court Decision? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Type of proponent: Private Public Governmental

Name of proponent: (person or organization) Department of Health

Name of agency personnel responsible for:

| | Name | Office Location | Phone |
|-----------------|-------------|---------------------------------------|--------------|
| Drafting: | Ross Valore | 111 Israel Road SE Tumwater, WA 98501 | 564-999-1060 |
| Implementation: | Ross Valore | 111 Israel Road SE Tumwater, WA 98501 | 564-999-1060 |
| Enforcement: | Ross Valore | 111 Israel Road SE Tumwater, WA 98501 | 564-999-1060 |

Is a school district fiscal impact statement required under [RCW 28A.305.135](#)? Yes No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Is a cost-benefit analysis required under [RCW 34.05.328](#)?

- Yes: A preliminary cost-benefit analysis may be obtained by contacting:
Name: Ross Valore
Address: PO Box 47852, Olympia, WA 98504-7852
Phone: 564--999-1060
Fax: n/a
TTY: 711
Email: cnrulemaking@doh.wa.gov
Other: <https://doh.wa.gov/licenses-permits-and-certificates/facilities-z/certificate-need>
- No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement

Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

(1) Identification of exemptions:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.061](#) because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570](#)(2) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025](#)(3). Check all that apply:

- | | |
|---|---|
| <input type="checkbox"/> RCW 34.05.310 (4)(b) (Internal government operations) | <input type="checkbox"/> RCW 34.05.310 (4)(e) (Dictated by statute) |
| <input type="checkbox"/> RCW 34.05.310 (4)(c) (Incorporation by reference) | <input type="checkbox"/> RCW 34.05.310 (4)(f) (Set or adjust fees) |
| <input checked="" type="checkbox"/> RCW 34.05.310 (4)(d) (Correct or clarify language) | <input type="checkbox"/> RCW 34.05.310 (4)(g) (i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit) |

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025](#)(4) (does not affect small businesses).

This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of how the above exemption(s) applies to the proposed rule: The rule proposal applies only to certificate of need approved kidney disease treatment centers. Certificate of Need approved kidney disease centers do not qualify as small businesses.

(2) Scope of exemptions: Check one.

- The rule proposal is fully exempt (*skip section 3*). Exemptions identified above apply to all portions of the rule proposal.
- The rule proposal is partially exempt (*complete section 3*). The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):
- The rule proposal is not exempt (*complete section 3*). No exemptions were identified above.

(3) Small business economic impact statement: Complete this section if any portion is not exempt.

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

- No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.
- Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name:

Address:

Phone:

Fax:

TTY:

Email:

Other:

Date: 4/30/2024

Name: Kristin Peterson, JD for Umair A. Shah, MD, MPH

Title: Chief of Policy for Secretary of Health

Signature:

A handwritten signature in cursive script that reads "Kristin Peterson".

WAC 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))~~ 10 percent but less than ~~((one hundred))~~ 100 percent ownership in a kidney dialysis facility;
 - (b) Having at least a ~~((ten))~~ 10 percent but less than ~~((one hundred))~~ 100 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 31st 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)~~) centers 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)~~) 75 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)~~) 3,325 square feet.

(12) "Network" means end stage renal disease (ESRD) Network 16.

(13) "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))~~ (14) "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))~~ (15) "Permanent bed station" means a bed that would commonly be used in a health care setting.

~~((15))~~ (16) "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))~~ 12 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 |

| KING SEVEN | KING EIGHT | KING NINE |
|---------------------|-------------------|------------------|
| 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 |

| SNOHOMISH ONE | SNOHOMISH TWO | SNOHOMISH THREE |
|---------------------|--------------------|-------------------------|
| 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))~~ (17) "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))~~ (18) "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))~~ (19) "Quintile" means any of five groups into which a population can be divided according to the distribution of values of a particular variable.

~~((19))~~ (20) "Resident in-center patients" means in-center hemodialysis (HD) patients who reside within the planning area. If more than ~~((fifty))~~ 50 percent of a kidney dialysis facility's patients re-

side outside Washington state, these out-of-state patients would be considered resident in-center patients.

~~((20))~~ (21) "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))~~ (22) "Temporary emergency situation" means a temporary emergency situation as defined in RCW 70.38.280 and WAC 246-310-825.

(23) "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).

AMENDATORY SECTION (Amending WSR 17-04-062, filed 1/27/17, effective 1/1/18)

WAC 246-310-803 Kidney disease treatment ((facilities)) centers
—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))~~ 10 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))~~ 10 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.

AMENDATORY SECTION (Amending WSR 17-04-062, filed 1/27/17, effective 1/1/18)

WAC 246-310-806 Kidney disease treatment ((facilities)) centers
—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:

| Concurrent Review Cycle | Letters of Intent Due | Application Submission Period | | | Department Action | Application Review Period | | |
|-------------------------|---|---|--|---|---|---|-------------------------------|-------------------------------|
| | | Receipt of Initial Application | End of Screening Period | Applicant Response | | 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). | 7-Day Rebuttal period. | 15-Day Exparte period. |

| Concurrent Review Cycle | Letters of Intent Due | Application Submission Period | | | Department Action | Application Review Period | | |
|----------------------------------|--|--|---|---|---|---|--|--|
| | | Receipt of Initial Application | End of Screening Period | Applicant Response | | Public Comment Period (includes public hearing if requested) | Rebuttal Period | Exparte Period |
| | | | | | | Begins June 23 or the first working day thereafter | Applicant and affected party response to public comment. | 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)) 15 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.

AMENDATORY SECTION (Amending WSR 17-04-062, filed 1/27/17, effective 1/1/18)

WAC 246-310-812 Kidney disease treatment ((facilities)) centers
—**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), nor does it include any dialysis stations added during a temporary emergency situation. For example, a kidney dialysis facility that is certificate of need approved and certified for (~~eleven~~) 11 stations would subtract the one exempt isolation station and use (~~ten~~) 10 stations for the methodology calculations.

(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 situation stations; or

(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; or

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

(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 situation stations; or

(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.

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; or

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

(7) If a facility was affected by a temporary emergency situation other than a staffing shortage, the department will continue to include the affected facility's total number of certificate of need approved permanent stations in the supply for the planning area, unless, in the department's discretion, including the affected facility's sta-

tions in the supply would negatively impact access to dialysis services.

(8) 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~~) the Network.

~~((8))~~ (9) 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.

AMENDATORY SECTION (Amending WSR 17-04-062, filed 1/27/17, effective 1/1/18)

WAC 246-310-815 Kidney disease treatment (~~(facilities)~~) centers
—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 a 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.

WAC 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 shelved 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 246-310-825 and RCW 70.38.280.

(a) All calculations described in this section exclude temporary emergency stations.

(b) A facility that operated temporary emergency stations due to a staffing shortage emergency situation, during the most recent six consecutive month period preceding the letter of intent submission date, is eligible to apply for special circumstances, if it has met all eligibility criteria described in this section. Facilities operating temporary emergency stations during this period for temporary emergency situations other than staffing shortages are ineligible for special circumstance expansions.

(c) Pursuant to RCW 70.38.280 (2)(d), a facility that operated temporary emergency stations due to a staffing shortage emergency situation may not exceed the number of patients served at the time of the exemption request. All calculations described in this section for the

review of a facility that operated temporary emergency stations due to staffing shortage emergency will have its patient census reported in the Network data limited to a maximum of the patients served at the time of the emergency request for the months when the temporary emergency was in effect.

AMENDATORY SECTION (Amending WSR 17-04-062, filed 1/27/17, effective 1/1/18)

WAC 246-310-821 Kidney disease treatment ((facilities)) centers—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.

AMENDATORY SECTION (Amending WSR 17-04-062, filed 1/27/17, effective 1/1/18)

WAC 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) All other applicable review criteria and standards have been met; and

(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

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

NEW SECTION

WAC 246-310-825 Kidney disease treatment centers—Temporary emergency situation exemption. The department may grant a kidney disease treatment center an exemption to exceed its authorized number of dialysis stations during a temporary emergency situation.

(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; and

(b) Any other temporary emergency situations that in the department's discretion constitute a "temporary emergency situation."

(2) For purposes of RCW 70.38.280 (2)(d), the following definitions apply:

(a) "Staffing shortage" means that kidney disease treatment center does not have sufficient staff to safely provide treatment.

(b) "Reconfiguration" means the addition of dialysis stations to facilitate the delivery of dialysis services, provided 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). 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) For temporary emergency situations other than those caused by staffing shortages, identify each facility expected to be affected by the temporary emergency situation. Facilities expected to be affected by the temporary emergency situation includes the facility requesting temporary emergency stations and any facility that suspends operations due to circumstances that qualify as a temporary emergency situation;

(c) The number of stations the facility intends to add during the duration of the temporary emergency situation;

(d) The number of shifts the facility proposes to operate during the duration of the temporary emergency situation; and

(e) Whether a capital expenditure will be made to remedy the temporary emergency situation.

(4) 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.

(5) 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, only if partial or full facility closure is due to circumstances that qualify under WAC 246-310-825(1) and the department approves a temporary emergency situation exemption request. The facility may restore its full approved stations once the temporary emergency has ended without having to reapply for certificate of need approval.

AMENDATORY SECTION (Amending WSR 17-04-062, filed 1/27/17, effective 1/1/18)

WAC 246-310-827 Kidney disease treatment ((facilities)) centers —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 |

| Data Item | Source |
|--------------------------------------|---|
| 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 non-quintile 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))~~ 80 percent or higher get five points.

(B) Dialysis facilities with a percentile ranking less than ~~((eighty))~~ 80 percent and greater than or equal to ~~((sixty))~~ 60 percent get four points.

(C) Dialysis facilities with a percentile ranking less than ~~((sixty))~~ 60 percent and greater than or equal to ~~((forty))~~ 40 percent get three points.

(D) Dialysis facilities with a percentile ranking less than ~~((forty))~~ 40 percent and greater than or equal to ~~((twenty))~~ 20 percent get two points.

(E) Dialysis facilities with a percentile ranking below ~~((twenty))~~ 20 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))~~ 80 percent or higher get one point.

(B) Dialysis facilities with a percentile ranking less than ~~((eighty))~~ 80 percent and greater than or equal to ~~((sixty))~~ 60 percent get two points.

(C) Dialysis facilities with a percentile ranking less than ~~((sixty))~~ 60 percent and greater than or equal to ~~((forty))~~ 40 percent get three points.

(D) Dialysis facilities with a percentile ranking less than ~~((forty))~~ 40 percent and greater than or equal to ~~((twenty))~~ 20 percent get four points.

(E) Dialysis facilities with a percentile ranking below ~~((twenty))~~ 20 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. | |

| Data Items: | Calculation of Points | Score |
|---------------------------------------|--|--------------|
| 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.

**WAC 246-310-830 Kidney disease treatment ((facilities)) centers
—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.

AMENDATORY SECTION (Amending WSR 17-04-062, filed 1/27/17, effective 1/1/18)

WAC 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.