

**Workbook for October 17 Rule Workshop**

<b>Agenda:</b>	<ul style="list-style-type: none"> <li>• Welcome and review of September 28 rule workshop</li> <li>• Draft language discussion</li> <li>• Additional rule workshops</li> </ul>
----------------	--

WAC Section	Public comment: Draft rule language	CN Response	Draft Language	Action items
<a href="#">WAC 246-310-800</a> Kidney disease treatment center – Definitions	No comments		No draft language added to section	Uses “center” rather than “facility” for section title.  Should all references to “Northwest Renal Network” be amended to state “Comagine?”
<a href="#">WAC 246-310-803</a> Kidney disease treatment facilities – Data reporting requirements	No comments		No draft language added to section	None
<a href="#">WAC 246-310-806</a> Kidney disease treatment facilities – concurrent review cycles	<a href="#">Fresenius</a> : Remove draft language from 806 stating that temporary emergency situation exemption request not subject to concurrent review cycles and move to section 806(10).	Removed draft language from section.	<b>Removed the following draft language:</b>  (10) Written requests by a kidney disease treatment center for additional dialysis stations sue to a temporary emergency situation pursuant to WAC 246-310-824(2) are not subject to the concurrent review timelines.	None
<a href="#">WAC 246-310-809</a> One-time exempt isolation station reconciliation	No comments		No draft language added to section	None
<a href="#">WAC 246-310-812</a> Kidney disease treatment facilities – Methodology	<a href="#">Fresenius Comments</a> :  <b>Add to (4)(d)</b> : (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-	Added recommended changes* to 812 to draft rule.  *2 Notes –  *CN changed reference from WAC 246-310-825 to RCW 70.38.280 when referring to temporary emergency situation exemption.	<b>Added the following language to (4)(d)</b> : <i>“and dialysis stations added during a temporary emergency situation defined in WAC 246-310-824(2).”</i>  <b>Added the following language to (5)(a)</b> : <i>“excluding temporary emergency stations defined in WAC 246-310-836”</i>  <b>Add new subsection (5)(c)</b> : <i>A facility was affected by a temporary emergency, as defined</i>	Will need to update reference to new standalone temporary emergency situation section.

	<p>310-800(9) and dialysis stations added during a temporary emergency situation defined in 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.</p> <p><b>Add to (5)(a):</b> (a) All stations for a facility have been in operation for at least three years, <i>excluding temporary emergency stations defined in WAC 246-310-836</i>; or</p> <p><b><u>New subsection (5)(c):</u></b> (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.</p> <p><b>Add to (6)(a):</b> (a) All stations for a facility have been in operation for at least three years, <i>excluding temporary emergency stations defined in WAC 246-310-836</i>; or</p> <p><b><u>New subsection (6)(c):</u></b> (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.</p>	<p>*CN changed citation of new section created for temporary emergency situation exemption from 246-310-836 to 246-310-825 in draft rule.</p>	<p><i>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.</i></p> <p><b>Added the following language to (6)(a):</b>  <i>“excluding temporary emergency stations defined in WAC 246-310-836”</i></p> <p><b>Add new subsection (6)(c):</b> <i>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.</i></p>	
<p><a href="#">WAC 246-310-815</a> Kidney disease</p>	<p>No comments</p>		<p>(1)(a) – fix grammatical error. Add “a” to (1)(a).</p>	<p>None</p>

treatment facilities – Financial feasibility			(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.	
<p><a href="#">WAC 246-310-818</a> Special circumstances one-or two-station expansion- Eligibility criteria and application process.</p>	<p><a href="#">Fresenius Comments:</a> <b>New subsection (14):</b> The department will review special circumstance requests with the following considerations related to temporary emergency stations defined in WAC 246-310-825: (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).</p>	<p>Added (14) but did not include proposed (14)(b). Unclear why kidney dialysis facilities who have request exemption due to staffing shortage would be able to apply for special circumstances but facility who closed due to natural disaster could not apply for special circumstances.  *CN changed reference from WAC 246-310-825 to RCW 70.38.280 when referring to temporary emergency situation exemption.</p>	<p>Add new subsection (14): <i>The department will review special circumstance requests with the following considerations related to temporary emergency stations defined in WAC 246-310-825:</i> (a) <i>All calculations described in this section exclude temporary emergency stations.</i> (b) <i>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).</i></p>	
<p><a href="#">WAC 246-310-821</a> Kidney disease treatment facilities- Standards for planning areas without an existing facility</p>	No comments		No draft language added to section	None
<p><a href="#">WAC 246-310-824</a> Kidney disease treatment centers - exceptions</p>	Comments during rule workshop #1 that temporary emergency situation exemption should have its own section.	Removed draft language from WAC 246-310-824 and moved to new	<p>Removed the following draft language:  (2) A kidney disease treatment center is granted an exemption to</p>	Uses “center” rather than “facility” for section title.

		<p>section WAC 246-310-825.</p>	<p>exceed its authorized number of dialysis stations during a temporary emergency situation, as defined by RCW 70.38.XXX.</p> <p>(a) In addition to the temporary emergency situations identified in RCW 70.38.XXX(2), the following are defined as temporary emergency situations:</p> <p>(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.</p> <p>(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:</p> <p>(i) A specific description of the actions the kidney disease treatment center will take to address the temporary emergency situation.</p> <p>(ii) A description of any patient harm that occurred due to the temporary emergency situation.</p> <p>(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).</p> <p>(e) A kidney disease treatment center may submit a temporary emergency situation exemption request at any time and is not</p>	
--	--	---------------------------------	--	--

			subject to the concurrent review cycles for kidney disease treatment centers in WAC 246-310-806.	
<p><b>NEW SECTION</b></p> <p>WAC 246-310-825 Temporary Emergency Situation Exemption</p>	<p><u>Fresenius Comments:</u></p> <p>See p. 30-38 <u>Fresenius Comments</u> for on proposed rule language.</p> <p>Add NEW temporary emergency situation exemption section.</p> <p>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.</p> <p>(1) In addition to the temporary emergency situations identified in RCW 70.38.280(2), the following are defined as temporary emergency situations:</p> <p>(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;</p> <p>(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</p> <p>(c) Severe disruption to transportation infrastructure like roads, bridges, or public</p>	<p>Added language proposed by <b>Fresenius with the following exceptions:</b></p> <p>(1)(b) – removed facilities already have isolation station(s) meant for this exact reason.</p> <p>(3) – removed “Written requests may be sent by email.” Duplicative with <u>RCW 70.38.280(3)</u>.</p> <p>(2)(a) – Added definition of “staffing shortage.”</p> <p>(4) – Added “reasonable efforts to issue”</p> <p>(4)(a) – <b>Removed.</b> Decision letters are based on our applications, if a facility is not represented in an application, then we do not write about it. This is incumbent on the applicant to tell us what the need and why, our decision letters would be reflective of what we're approving and why.</p> <p>Added “complete” written request.</p> <p>(6) – <b>Removed</b> “in part or in its entirety”</p>	<p>Added the following language:</p> <p>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.</p> <p>(1) In addition to the temporary emergency situations identified in RCW 70.38.280(2), the following are defined as temporary emergency situations:</p> <p>(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;</p> <p>(b) Severe disruption to transportation infrastructure like roads, bridges, or public transit that severely limits patient access to facilities.</p> <p>(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.</p> <p>(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:</p> <p>(a) A specific description of the actions the kidney disease treatment center will take to</p>	

	<p>transit that severely limits patient access to facilities.</p> <p>(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.</p> <p>(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:</p> <p>(a) A specific description of the actions the kidney disease treatment center will take to address the temporary emergency situation.</p> <p>(b) A description of any patient harm that has or is reasonably expected to occur due to the temporary emergency situation.</p> <p>(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).</p> <p>(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</p>	<p>(6) - Added “only if partial or full facility closure is due to circumstances that qualify as a temporary emergency situation and the department approves a temporary emergency situation exemption request directly related to the partial or full facility closure.”</p> <p>(7) – Removed “This information will be published on the department’s website within five working days of receipt of the written request and within five working days of the department’s decision.</p>	<p>address the temporary emergency situation.</p> <p>(b) A description of any patient harm that has or is reasonably expected to occur due to the temporary emergency situation.</p> <p>(4) The department will make reasonable efforts to issue a decision within three working days of receipt of a facility’s written request for temporary emergency stations, as described in subsection (3).</p> <p>(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.</p> <p>(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.</p> <p>(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, only if partial or full facility closure is due to circumstances that qualify as a temporary emergency situation and the department approves a temporary emergency situation exemption request directly related to the partial or full facility closure. The facility may restore its full</p>	
--	---	--	---	--

	<p>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.</p> <p>(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.</p> <p>(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.</p> <p>(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</p>		<p>authorized operations once the temporary emergency has ended without having to reapply for certificate of need approval.</p> <p>(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.</p>	
--	---	--	---	--

	within five working days of the department's decision.			
<a href="#">WAC 246-310-827</a> Kidney disease treatment facilities – superiority criteria	No comments.		No draft language added to section	None
<a href="#">WAC 246-310-830</a> Kidney disease treatment facilities— Relocation of facilities	No comments.		No draft language added to section	None
<a href="#">WAC 246-310-833</a> One-time state border kidney dialysis facility station relocation	No comments.		No draft language added to section	None