

Significant Legislative Rule Analysis

for Chapter 246-310- WAC
Rules Concerning Kidney Disease
Treatment Centers

June 2016

SECTION 1:

Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

The proposed rules provide substantive guidance regarding the kidney disease treatment center application review process by fully describing and clarifying the existing methodology for predicting future need for kidney dialysis treatment centers. The rules do not create any new regulatory or compliance burdens on existing or future kidney dialysis disease treatment centers. Designed to clarify the current kidney disease treatment facility methodology, the proposed rules serve as a guide and clearly describe the department's decision-making process regarding the establishment and expansion of kidney dialysis facilities. These proposals are consistent with the purpose of the Certificate of Need (CoN) statute.

The Department of Health (department) administers the CoN program under chapter 70.38 RCW and chapter 246-310 WAC. The primary goals of the CoN program are to control costs by assuring that existing facilities are fully utilized before additional facilities are added, and to promote patient access to quality care consistent with RCW 70.38.015. Additionally, RCW 70.38.105(4)(a) requires an entity to obtain a CoN prior to constructing, developing or otherwise establishing certain health care facilities and services.

Under RCW 70.38.025(6), a kidney disease treatment center is one type of health care facility requiring CoN approval. RCW 70.38.105(4)(h) provides that any increase in the number of dialysis stations in a kidney disease treatment center is subject to CoN review. For kidney disease treatment center applications, the department has adopted a methodology described in WAC 246-310-284 to determine the number of stations that will be needed in the future to serve patients in the planning area where the facility would be located. Under this methodology, a kidney disease treatment center is approved for a specific number of dialysis stations. This concept of approving specific capacity is consistent with the purpose of the CoN statute to control health care costs by making sure that existing capacity is fully utilized before additional capacity is added. The current kidney disease treatment center rules and methodology were adopted in January 2007. In November 2012, the department received a rules petition requesting review of these rules.

The department is proposing repealing WAC 246-310-280, 246-310-282, 246-310-284, 246-310-286, 246-310-287, 246-310-288, and 246-310-289. To reorganize and update this chapter, the department proposes adding WAC 246-310-800, -803, -806, -809, -812, 815, -818, -821, -824, -827, -830, and -832.

The proposed modifications require repeal of the above referenced rules. Proposed reorganization is described in the following table:

Existing WAC (To be Repealed)	Proposed New WAC
WAC 246-310-280- Kidney disease treatment centers – Definitions.	WAC 246-310-800- Kidney disease treatment centers – Definitions.

N/A-	WAC 246-310-803 – Kidney disease treatment centers – data reporting requirements.
WAC 246-310-282 – Kidney disease treatment centers – Concurrent review cycle.	WAC 246-310-806- Kidney disease treatment centers – Concurrent review cycle.
N/A	WAC 246-310-809 – One-time exempt isolation station reconciliation.
WAC 246-310-284 – Kidney disease treatment centers-Methodology	WAC 246-310-812 – Kidney disease treatment centers-Methodology.
N/A	WAC 246-310-815- Kidney disease treatment centers-Financial feasibility.
N/A	WAC 246-310-818-Special circumstances one or two-station expansion-Eligibility criteria and application process.
WAC 246-310-286-Kidney disease treatment centers-Standards for planning areas without an existing facility.	WAC 246-310-821-Kidney disease treatment centers-standards for planning areas without an existing facility.
WAC 246-310-287-Kidney disease treatment centers-Exceptions.	WAC 246-310-824-Kidney disease treatment centers – Exceptions.
WAC 246-310-288-Kidney disease treatment centers-Tie-breakers	WAC 246-310-827-Kidney disease treatment centers-Superiority Criteria.
WAC 246-310-289-Kidney disease treatment centers-Relocation of facilities	WAC 246-310-830-Kidney disease treatment centers-Relocation of facilities.
N/A	WAC 246-310-833-One-time state border dialysis facility station relocation.

Clarification and modernization of the rules is needed to increase predictable, consistent and enforceable CoN decisions, supporting fulfillment of the legislative intent that requires CoN approval for kidney disease treatment centers. Clarity and clearly articulated guidance will assist in the reduction of litigation and related expenses.

SECTION 2:

Is a Significant Analysis required for this rule?

The proposed rules clarify department processes and practices for review of Certificate of Need kidney dialysis treatment center applications, which is required for department approval to construct or expand kidney dialysis treatment facilities. Portions of this rule set require significant analysis as defined by RCW 34.05.328. However, the department has determined that no significant analysis is required for the following portions of the rule:

WAC with no significant impact	Justification
WAC 246-310-280 (Proposed WAC 246-310-800) – Kidney dialysis treatment centers – Definitions	Does not meet the definition of a significant legislative rule under RCW 34.05.328(5)(c).
WAC 246-310-815 – Kidney disease treatment centers – Financial Feasibility.	RCW 34.05.328(5)(b)(iv) Clarification (describes and clarifies existing criteria used by the department when evaluating the financial feasibility of kidney disease treatments centers pursuant to WAC 246-310-220).
WAC 246-310-818 – Special circumstances one or two-station expansion – Eligibility criteria and application process.	RCW 34.05.328(5)(b)(iv) Clarification (describes, clarifies and articulates existing rules regarding how the department evaluates special circumstances and two-station expansion).
246-310-286 (Proposed WAC 246-310-821)– Kidney disease treatment centers – Standards for planning areas without an existing facility.	RCW 35.05.328(5)(b)(iv) Clarification (added a county to planning areas without existing kidney dialysis facilities).
246-310-287 (Proposed WAC 246-310-824) Kidney disease treatment centers – Exceptions.	RCW 34.05.328(5)(b)(iv) Clarification (added reference to WAC 246-310-285B regarding one or two-station expansion).
WAC 246-310-289 (Proposed WAC 246-310-830) –	RCW 34.05.328(5)(b)(iv) Clarification (clarified applicable

SECTION 3:

Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

The goals and objectives of chapter 70.38 RCW are to “promote, maintain and assure the health of all citizens in the state, to provide accessible health services, health manpower, health facilities, and other resources while controlling excessive increases in costs.” The statute states that health planning “should be concerned with public health and health care financing, access and quality, recognizing their close interrelationship and emphasizing cost controls of health services, including cost effectiveness and cost-benefit analysis.”

The proposed rules implement the statute’s objective and authority by:

- A. Defining clear decision making processes and standards;
- B. Amending such rules as are necessary to provide the best public health and welfare;
- C. Supporting the overarching goal of chapter 70.38 RCW to make sure the development or expansion of healthcare services is accomplished in a planned and orderly fashion, without unnecessary duplication while promoting access to quality, cost effective services.

SECTION 4:

Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.

The basic goals of the CoN program – quality, cost containment and patient experience – are realized by clearly articulated rules. The department determined that the proposed rules are needed to achieve the goals and objectives of CoN because they provide well-defined guidance to providers and succinctly describe the department’s decision-making process regarding the construction and expansion of kidney dialysis facilities. The proposed rules represent the department’s commitment to achieve its statutorily defined goals and objectives.

This rule set does not create or increase regulatory burden to kidney disease treatment center providers. The proposed rules provide substantive guidance regarding the kidney disease treatment center application review process by fully describing and clarifying the existing methodology for predicting future need for kidney dialysis treatment centers. Stakeholders agreed that rulemaking was appropriate to promote clear, consistent and

timely decisions. Rulemaking provides applicants and affected parties with articulately described decision-making guidance, succinctly explained. If the proposed rules are not adopted, the current rules do not consider the current and continued evolution of healthcare landscape, including increased need for patient access to kidney dialysis services.

SECTION 5:

Explain how the department determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The portions of the rule that are significant are analyzed in the numbered list below. As noted above, portions of the rules that are not significant are excluded from this analysis.

1. *Proposed New Section - WAC 246-310-803* – Kidney disease treatment centers – data reporting requirements.

Description: Providers annually submit cost reports to the Centers for Medicare and Medicaid Services (CMS). Providers annually receive kidney dialysis facility reports from CMS. Providers submit specific pages from each of these reports to the department. These documents assist the department in concurrent review application evaluation. The existing rule does not identify the specific reports and which parts of the reports should be submitted to the department. Further, the existing rule does not identify consequences associated with failure to submit complete reports, submission of incomplete reports, and does not provide guidance regarding how to request an exemption from reporting.

The proposed rule clearly identifies reporting requirements, and identifies each page that must be submitted from each report as follows:

- 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
- 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.

The proposed rule further establishes submission deadlines, identifies entities required to submit cost and dialysis facility reports, and describes consequences for submission of incomplete reports as well as failure to submit reports. The proposed rule also describes how a provider may request an exemption from reporting.

Cost/Benefit Analysis:

The proposed rule creates two administrative tasks that were not required under the existing rule. There is a potential for a third administrative task in the event that the provider requests an exemption from subsection (2) of this section. The worksheets requested are readily and easily available to providers.

The first administrative task involves electronically submitting two worksheets to the department. Electronic submission means email and/or facsimile submission that does not require the acquisition of a special computing platform or software. Similarly, the documents submitted can be provided in Portable Document Format (PDF) or Word format, and neither of these file formats require a special computing platform or software.

In the event that one of these two reports is unavailable to the provider within the identified reporting window, the proposed rule describes how providers can request an exception allowing submission the required information after the identified deadline.

The proposed rule provides benefit by clearly identifying the data reports providers must submit to the department, by setting a deadline for the submission of those reports, and by describing the consequences of failure to report. It offers providers the benefit of objective evaluation and unbiased measurement of supporting documents used as part of the department's evaluation process. There are no anticipated administrative costs.

2. Proposed New Section - WAC 246-310-806 (To Repeal WAC 246-310-282) – Kidney dialysis treatment centers – Concurrent review cycle.

Description: The department reviews kidney dialysis facility applications using a concurrent review cycle described in WAC 246-310-120 and authorized by RCW 70.38.115(7). Concurrent review is for the purpose of comparative analysis and evaluation of competing or similar projects in a planning area to determine which of the projects may best meet identified need. The department compares applications to one another and the rules to determine the superior alternative. The department has provided additional guidance and clarity regarding the review process, including a thorough and detailed description of how superiority is determined.

Cost/Benefit Analysis:

There is no cost associated with this rule. The rule provides public benefit because it describes and guides providers through the department's superiority analysis. This will assist the department in producing timely decisions based on consistent

application of the rules. The rule provides additional benefit to providers by clarifying existing guidelines and promoting the orderly development of health care facilities pursuant to RCW 70.38.015.

3. *Proposed New Section - WAC 246-310-809 – One-time exempt isolation station reconciliation.*

Description: CMS ESRD Conditions of Coverage require an isolation station within an isolation room for dialyzing hepatitis B+ patients. The department will make a one-time administrative adjustment to each dialysis facility to add one station as an approved exempt isolation station for facilities issued a certificate of need prior to the effective date of this rule. The department will identify each kidney dialysis treatment facility and the total number of CoN approved stations as of the effective date of the rule. Then, the department will make a one-time administrative station adjustment to each dialysis facility, adding one approved exempt isolation station to each facility, and notifying each facility of its adjusted CoN approved station count.

This rule supports the department's legal authority to make this adjustment.

Cost/Benefit Analysis:

There is no cost associated with this rule. The rule benefits providers by clarifying when and how the department will adjust for exempt isolation stations. There are no additional regulatory burdens or requirements imposed on providers. The benefit to providers outweighs any potential cost providers may incur.

4. *Proposed New Section - WAC 246-310-812 (To Repeal WAC 246-310-284) – Kidney disease treatment centers – Methodology.*

Description: The current need methodology went into effect in January 2007. The proposed rule does not significantly alter, revise or modify the current methodology. The proposed rule adds clarity and guidance to the existing rule by changing the following:

- The process the department uses to calculate net station need. The new rule extends the projection horizon from four years to five years.
- How the department counts stations. A facility's station count no longer includes one isolation station for determining station capacity in the numeric methodology.
- The department standard for existing facility station use rates. In the existing rule, all stations had to be operating at 4.8 patients per station before any new stations could be added. The revised rule reduces this number to 4.5 patients per station.

- Added criteria when applications can be approved to add stations in a planning area when existing facilities are not meeting the station use standards.

Cost/Benefit Analysis:

There is no cost associated with this rule. The rule does not impose any regulatory burden on providers, nor does it change, modify, add cost or otherwise alter the CoN application evaluation process. Rather, it clearly explains the department's evaluation process for facilities meeting the in-center patient per station standard while defining how stations are counted for purposes of need projection methodology within identified planning areas. This clarification of standards and process is beneficial because it is designed to reflect differences among communities to meet patient needs. It promotes reliable, cost-effective planning, achieving the CoN goal of patient and community access to quality care while providing clear expectations and criteria by which applications are evaluated. The department does not expect any unintended consequences of implementation.

5. Proposed New Section - WAC 246-310-818 – Special circumstances for one or two-station expansion – Eligibility criteria and application process.

Description: This section articulates and describes dialysis facility special circumstance eligibility and the associated application process. Specifically, subsection (2) describes when the department may approve a special circumstance station expansion, even when other facilities not owned and operated by the applicant are operating below the minimum patient standard for the planning area. The facility must be able to accommodate the additional stations within its existing structure or building, and if renovation is required, it must occur within the existing structure or building.

The purpose of the special circumstances one or two station expansion concept is to allow facilities that are at or near capacity to expand by one or two stations when there is no numeric need identified within that planning area. This serves two important, linked purposes. First, it provides limited station expansion under narrow circumstances, allowing providers to timely respond to patient need. Second, and more importantly, it acts essentially as a “relief valve” for patients by supporting their choice of provider and enabling continuity of care.

Cost/Benefit Analysis

There is no cost associated with this rule. The measures identified in this section articulate and describe the department's evaluation process for special circumstances expansion. This rule is designed to provide for limited expansion and support patient need, increasing and supporting access to care. Providers may incur additional renovation costs to accommodate constructing additional stations within

their existing structures. However, this cost is not imposed by the department or this rule.

6. *Proposed New Section - WAC 246-310-827 (To Repeal WAC 246-310-288)– Kidney disease treatment centers – Superiority Criteria.*

Description: The measures identified in this section articulate and describe the department’s superiority evaluation process, formerly termed “tie breakers.” For purposes of WAC 246-310-240(1), (cost containment), if two or more applications meet all applicable review criteria and there is not enough station need for all applications to be approved, the department will use superiority criteria to determine which application or applications will be approved. The proposed rule clarifies and provides additional guidance to existing rule.

Cost/Benefit Analysis:

There is no cost associated with this rule. This rule does not impose a new regulatory compliance burden on providers. It clarifies the process the department uses to determine superiority of competing applications in specified planning areas. The department expects to eliminate adjudicative appeals associated with cost containment arguments. The department does not expect any unintended consequences of implementation.

7. *Proposed New Section - WAC 246-310-833 – One-time state border dialysis facility station relocation.*

Description: This rule clarifies the conditions and circumstances related to the operation of state boarder dialysis facilities in contiguous Oregon and Idaho counties. Identifying affected counties, the rule provides guidance as to the application of WAC 246-310-020(1), describing when a Washington facility and an out-of-state facility combine to create a new health care facility, and outlining specific criteria for a one-time exemption.

Cost/Benefit Analysis

There is no cost associated with this rule. This rule does not impose any regulatory burden on providers. The rule clarifies how the department determines one-time state border dialysis facility station relocation. The rule benefits the public not only by supporting continuation of patient care, but by making sure that existing facilities located on Washington’s borders can continue to operate. These facilities can then support existing and future need while maintaining access to needed dialysis services.

Cost Benefit Summary

Providers generally incur costs to construct, expand and operate kidney dialysis facilities. However, this proposed rule set does not create or impose any additional regulatory impact or cost. Rather, it reduces regulatory compliance burden to providers by fully and concisely describing the department's decision-making processes, while modernizing and simplifying the application process. These rules are responsive to the changing healthcare landscape, and designed to encourage managed growth of kidney dialysis facilities within the statutory authority of chapter 70.38 RCW. The proposed rules accomplish this by providing clear guidance to providers as they progress through the CoN application process.

The proposed rule changes will not result in any increase, nominal or substantial, to the total cost of constructing, expanding or relocating a kidney dialysis treatment center. The benefit of ensuring kidney dialysis treatment centers are built, expanded or relocated in compliance with rule exceeds any total probable costs.

SECTION 6:

Identify alternative versions of the rule that were considered, and explain how the department determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives state previously.

DOH staff worked closely with kidney dialysis treatment center providers, health facilities consultants and other constituents over a protracted period of time to minimize the burden of this rule. The department offered these stakeholders many opportunities to participate in rulemaking workshops, provide suggested rule changes and comments. During open public rules workshops, many versions of the rules were provided to the department. After careful consideration, some of the suggested changes were accepted while others were rejected. Mutual interests were identified and considered through deliberations.

Least burdensome determination

The department's stakeholdering process encouraged parties to:

- Identify burdensome areas of the existing rules;
- Propose initial or draft rule changes;
- Refine those changes.

The proposed rule changes went through several stages of edits, review, and discussion and then further refinement before arriving at the final proposal. The end result of this process are proposed changes that will provide increased rule clarity, guidance and will ultimately be less burdensome than the original rules.

Summarized below are brief descriptions of alternative versions of the analyzed portions of the rule set. The rules proposed are the least burdensome alternative for the entities required to comply, and will achieve the statutorily described general goals and specific objectives of RCW 70.38.

Alternate Versions Considered	Level of Burden
<p>1. <i>Proposed New Section - WAC 246-310-803</i> – Kidney disease treatment centers – data reporting requirements: workgroup members generally agreed that data sources and methods of acquiring data should be “clear,” although there were differing opinions as to the definition of “clear.” Through collaborative rulemaking, the proposed rule reflects agreement of the workgroup and the department.</p>	<p>The proposed rule may create minimal administrative burden. It identifies data elements providers must submit to the department and a period for submission. Those elements consist of two brief, publically accessible reports. The proposed rule creates two administrative tasks that were not required under the existing rule. There is a potential for a third administrative task in the event that the provider requests an exemption from subsection (2) of this section. The worksheets requested are readily and easily available to providers.</p>
<p>2. <i>Proposed New Section - WAC 246-310-806 (To Repeal WAC 246-310-282)</i> – Kidney dialysis treatment centers – Concurrent review cycle: the workgroup initially considered 3 concurrent review cycles. Through deliberation and collaborative rulemaking, the proposed 2-review concurrent review cycle was accepted by the group.</p>	<p>There is no burden associated with this rule. The rule provides public benefit because it describes and guides providers through the department’s superiority analysis. The rule provides additional benefit to providers by clarifying existing guidelines and assuring orderly development of health care facilities under RCW 70.38.015.</p>
<p>3. <i>Proposed New Section - WAC 246-310-809</i> – One-time exempt isolation station reconciliation: workgroup members initially provided a variety of revisions, including differing numbers of exempt isolation stations, and changing home dialysis to home training service recognition. Through deliberation and collaborative rulemaking, the proposed one-time exempt isolation station reconciliation was accepted by the group.</p>	<p>This rule does not impose regulatory burden or requirements on providers. The rule is a benefit to providers because the department clarifies when and how it will adjust for exempt isolation stations. The department will identify each kidney dialysis treatment facility and the total number of CoN approved stations as of the effective date of the rule. Then, the department will make a one-time administrative stations adjustment to each dialysis facility, adding one approved exempt isolation station to each facility, and notifying each facility of its adjusted CoN approved station count.</p>
<p>4. <i>Proposed New Section - WAC 246-310-812 (To Repeal WAC 246-310-284)</i> – Kidney disease treatment centers – Methodology: the workgroup prepared, reviewed and discussed multiple revisions to this rule. Considerable discussion occurred regarding projected station need and planning areas.</p>	<p>The rule does not impose regulatory burden on providers. It clarifies the department’s evaluation process for facilities meeting the in-center patient per station standard while defining how stations are counted for purposes of need projection methodology within identified planning areas.</p>
<p>5. <i>Proposed New Section - WAC 246-310-827 (To Repeal WAC 246-310-288)</i> – Kidney Disease Treatment Centers – Superiority Criteria: the workgroup prepared, reviewed and discussed multiple revisions to this rule. Considerable discussion occurred regarding net revenue per treatment, and weighting/scoring of quality measures.</p>	<p>This rule does not impose a new regulatory compliance burden on providers or stakeholders. It clarifies the process the department relies upon to determine superiority of competing applications in specified planning areas.</p>
<p>6. <i>Proposed New Section - WAC 246-310-833</i> – One-time state border dialysis facility station relocation: the workgroup discussed border-planning areas and developed language to address border state dialysis facility ownership in a contiguous Idaho or Oregon county.</p>	<p>This rule does not impose any regulatory burden on providers or stakeholders. The rule clarifies how the department determines one-time state border dialysis facility station relocation. The rule benefits the public by ensuring that existing facilities located on Washington’s borders can continue to operate while supporting existing and future need and maintaining access to needed dialysis services.</p>

SECTION 7:

Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The rule does not require those to whom it applies to take action that violates requirements of federal or state law.

SECTION 8:

Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities.

SECTION 9:

Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does not differ from any applicable federal regulation or statute.

SECTION 10:

Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no other applicable laws.