Significant Legislative Rule Analysis

WAC 246-310-020
A Rule Concerning Applicability of
Chapter 246-310 WAC – Expansion of
Certificate of Need-Approved Ambulatory
Surgical Facility Operating Rooms

July 2016

SECTON 1:

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

The Department of Health (department) administers the Certificate of Need (CoN) program pursuant to chapter 70.38 RCW and chapter 246-310 WAC. The primary goals of the CoN program are to control costs by making sure that existing facilities are fully utilized before additional facilities are added, and consistent with RCW 70.38.015(1), to "assure the health of all citizens in the state…" 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. For approval, RCW 70.38.115(2) (A) and WAC 246-310-210(1) provide that a CoN applicant must show that the population to be served has "need" for the proposed facility.

An ambulatory surgical facility (ASF) is a type of health care facility identified in RCW 70.38.025(6) that requires CoN approval before an applicant may build and operate such a facility. WAC 246-310-010(5) defines an ASF as a type of facility where surgery is performed to treat patients without requiring the patient to be hospitalized. As of 2015, there were 182 licensed ASFs in Washington state. For ASF applications, the department has adopted a methodology described in WAC 246-310-270 to determine the number of operating rooms that will be needed in the future to serve patients in the planning area. The methodology relies on knowing the number of CoN approved operating rooms and adjusting for three years of forecasted growth in the population served and trends in surgeries per capita. Under this methodology, an ASF is approved for a specific number of operating rooms. 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.

In the past, department decisions allowed ASFs to add a small number of operating rooms without CoN review. In 2012, the department began to interpret the CoN statute requiring review of ASF differently because the department realized that its prior allowance of operating room expansion without CoN review might not be consistent with the intent and purpose of the requirement for CoN review of ASFs. In 2014, representatives of an ASF requested a technical assistance meeting with the department with respect to the expansion of its CoN-approved three operating rooms to ten. Following this meeting, the department advised the ASF that the expansion required a CoN. The ASF challenged the department's statutory interpretation of "the construction, development, or other establishment of a new health care facility" in Thurston County Superior Court. The court ruled that while the statute provides the authority to require CoN review for expanding an ASF, the department must adopt the requirement in rule to implement its interpretation.

The department is proposing to change WAC 246-310-020 consistent with the court's decision to address the expansion of CoN-approved ASF operating rooms. The department opened its rules to clarify that a CoN-approved ASF seeking to increase the

number of CoN approved operating rooms constitutes the construction, development, or other establishment of a new health care facility, and is subject to CoN approval.

Clarification of the rule is needed to increase predictable, consistent and enforceable CoN decisions to promote better fulfillment of legislative intent in requiring CoN approval for ASFs.

SECTION 2:

Is a Significant Analysis required for this rule?

Yes, as described by RCW 34.05.328(5)(c)(iii)(B), the proposed rule requires a significant analysis because it establishes, alters, or revokes any qualification or standard for the issuance, suspension, or revocation or a license or permit.

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.”

More specifically, RCW 70.38.105(4)(a) provides that CoN review is required for the “construction, development, or other establishment of a new health care facility.” The proposed rule explains the applicability of these standards to ASFs.

The rule implements the statute’s objective by:

A. Clearly defining the circumstances under which CoN review is required for the “construction, development, or other establishment of a new healthcare facility” under RCW 70.38.105(4)(a);
B. Amending such rules as are necessary in the public interest;
C. Supporting the overarching goal of chapter 70.38 RCW to make sure that 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 rule is needed to achieve the goals and objectives of CoN because it clearly articulates and describes the circumstances under which the expansion of an ambulatory surgical facility becomes the construction, development, or other establishment of a new health care facility. The proposed rule represents the department's commitment to achieve its statutorily defined goals and objectives. Allowing the expansion of operating rooms by CoN-approved ASFs without further CoN review has the potential of resulting in the overexpansion of operating rooms. If this occurs, it defeats the initial analysis and results in the need to increase utilization of those operating rooms to recover its costs, triggering possible unnecessary, excess surgical demands, or the failure of ASFs due to inability to recover its costs. This has the potential to destabilize the health care market place in local communities. Rulemaking provides that CoN applicants and affected parties that program decisions are consistent and criteria are applied fairly and equitably, and that the public policy goals of CoN are better fulfilled.

The department explored other options to address the expansion of ambulatory surgical facilities, and determined that there are no feasible alternatives to rulemaking. To clarify the circumstances that constitute the construction, development, or other establishment of a new ASF meets the definition of a rule in RCW 34.05.010(16) and therefore, the clarification must be in rule to be enforceable. If the proposed rule is not adopted, the state faces potentially unregulated expansion of ASFs, resulting in a threat to the CoN goals of cost containment and patient access to quality, affordable healthcare services. The court found that the department must adopt a rule to support the department's policy interpretation to require CoN review when an existing ASF added surgical operating rooms. The proposed rule is consistent with the court's decision.

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 proposed rule amends WAC 246-310-020. By definition, the requirement in this rule is considered "legislatively significant" (RCW 34.05.328). The following is a cost/benefit analysis of the rule:

Rule Overview – WAC 246-310-020 – Applicability of chapter 246-310 WAC.

The proposed rule clarifies when chapter 246-310 WAC specifically applies to ASFs, and when the expansion of a CoN-approved ASF becomes the construction, development, or other establishment of a new health care facility.

Ambulatory surgical facilities are identified as a type of health care facility subject to CoN review under RCW 70.38.025(6). Entities are required to obtain a CoN prior to the construction, development, or other establishment of certain health care facilities and services as provided in RCW 70.38.105(4)(a).

WAC 246-310-010(5) defines "ambulatory" surgical facility as, "any freestanding entity, including an ambulatory surgical center" operating for the primary purpose of performing surgery on patients not requiring hospitalization… [t]his term does not apply to facilities in the offices of private physicians, whether individual or group practice if the privilege of using the facility is not extended to physicians…outside of the group practice." Accordingly, individual and group practice facilities may operate as licensed, non-CoN approved or CoN "exempt" facilities.

However, when a facility proposes to convert an existing non-CoN approved facility to a CoN approved facility, it is generally with the intent of allowing physicians outside of the practice access to the facility. This benefits patients by increasing and improving access to services through case volume expansion while expanding the capacity of outpatient ORs for physicians and their patients. Conversion also promotes quality and continuity of care, cost and operating efficiency.

Rule Cost/Benefit Analysis

The table below outlines the cost estimate of the proposed rule. Estimates provided in the table are from pro forma financials submitted as part of ASF CoN applications. The facilities reviewed for purposes of this analysis are identified as ASF #1, ASF #2 and ASF #3.

ASF #1 reflects data provided to support the one-operating room expansion of a CoN-approved ASF. This application was subsequently approved. ASF#2 and #3 reflect data provided to support the conversion of existing CoN-exempt ASFs to CoN-approved ASFs. Each of these applications was also approved.

Fields within the table are split into two groups: costs and revenues. Each sub-category is identified below and described as follows:

- **Costs:**
    - **One-time Application Fee**: CoN application and review fees are identified in WAC 246-310-990(b). Review fees are paid only once. Additional rules and fees apply when amending a pending CoN application. Fees may be refunded for reasons stated in rule, including by not limited to return of the application by the department or written withdrawal of the application.

- **Life of Application**: 15 years has been applied as the assumed life of the application based on the number of years a facility might potentially operate before contemplating expansion, or any other activity that may trigger CoN review.
- **Annual Application Fee**: This is the cost of the application fee spread over the assumed life of the application.

- **Revenues**
  - **Number of Operating Rooms, Year 2016**: These figures represent the total number of operating rooms reported in pro formas for each ASF applicant.
  - **Number of Operating Room Cases, Year 2016**: These figures represent the total number of operating room cases, often referred to as "procedures" reported in pro formas for each ASF applicant.
  - **Total Patient revenue Forecast, Year 2016**: These figures represent the gross patient revenue reported in pro formas for each ASF applicant.

ASF	**ASF #1**	**ASF #2**	**ASF #3**
Costs :			
One-time Application Fee	$20,427	$20,427	$20,427
Life of Application	15 Years	15 Years	15 Years
Annual Application Fee	$1,362	$1,362	$1,362
Revenues:			
Number of Operating Rooms, Year 2016	4.74	1.25	2.18
Number of Operating Room Cases, Year 2016	4,777	1,914	2,586

As the table indicates, the annual cost equivalent of the one-time application fee is $1,362. This is calculated by dividing the cost of the application ($20,427) by the assumed life of the application (15 years).

The proposed rule change is designed to provide clarity and direction to an existing process by adopting the department's current policy based on its interpretation of current law. While this could result in consultation fees related to the preparation of a CoN application that are unknown to the department, such fees are routine and customary to applicants. Similarly, the one-time application fee and potential administrative fees are not new costs to providers. However, under the proposed rule patients benefit by the assurance that ASFs will be expanded consistent with the intent of chapter 70.38 RCW, "…to provide accessible health services, health manpower, health facilities, and other resources while controlling excessive increases in 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.

Alternatives Considered

Alternative A – No Change in Current Rule Language (WAC 246-310-010(1)(a):

> (1) The following undertakings shall be subject to the provisions of chapter 246-310 WAC, with the exceptions provided in this section.
> (a) The construction, development or other establishment of a new health care facility;
> (i) No new health care facility may be initiated as a health service of an existing health care facility without certificate of need approval as a new health care facility;
> (ii) The provision of services by a home health agency or hospice to a county, on a regular and ongoing basis, that was not previously included in the home health agency or hospice service area shall be considered the development of a new home health agency or hospice;

Alternative A would not be consistent with the court's decision. ASFs wanting to expand surgical operating rooms would not have clear guidance to know when CoN review of the proposed expansion is required. ASFs choosing to expand the number of operating rooms without seeking CoN review would not pay the CoN application fee or other costs specifically associated with pursuing a CoN application.

Alternative B: First draft of language considered as new subsection (1)(a)(iii):

> (iii) *Whenever an existing ambulatory surgery facility proposed to expand the number of certificate of need-approved operating rooms at the facility, the proposed expansion constitutes the construction, development or other establishment of a new health care facility subject to certificate of need approval under RCW 70.38.105(4)(a). An existing ambulatory surgery facility may not exceed the number of operating rooms approved on its certificate of need or approved in the department's certificate of need evaluation.*

In Alternative B, the department clarifies when the expansion of a CoN-approved ASF becomes the construction, development or other development of a new healthcare facility and is therefore subject CoN review. However, this language did not address the period of time prior to July 1, 2009, when ASFs were not licensed and had received a Determination of Reviewability from the CoN program pursuant to WAC 246-310-050, or facilities that had received Construction Review Services approval prior to the effective date of the proposed rule.

This version of the rule was presented to stakeholders. The feedback from the stakeholders identified a potentially overly restrictive interpretation that would have required unintended retroactive application reviews. This resulted in Alternative C, which the department believes is the least burdensome of the three alternatives that meets the goals and objectives of the underlying statute chapter 70.38 RCW.

Alternative C –Second draft of language considered as new subsection (1)(a)(iii):

(iii) Any certificate of need approved ambulatory surgical facility expanding the number of operating rooms shall be considered the construction, development or other establishment of a new ambulatory surgery facility. After the effective date of these rules, a certificate of need approved ambulatory surgical facility may not operate more than the number of operating rooms approved by the department identified on its certificate of need or approved in the department evaluation. A certificate of need approved ambulatory surgery facility that:

(A) Received Construction Review Services approval to begin construction prior to the effective date of these rules to add operating rooms at its facility is not required to obtain additional certificate of need approval for those operating rooms only. Or

(B) Received a Determination of Reviewability prior to July 1, 2009, that adding operating rooms at its facility did not require certificate of need approval, is not required to obtain additional certificate of need approval for those operating rooms based on that determination provided that the operating rooms were completed prior to the effective date of these rules or meets (A) of this subsection.

Alternative D – Proposed Language:

This version of the language was developed during internal work sessions in collaboration and consultation with assigned assistant attorney general staff in an effort to streamline, simplify and clarify the rule:

(iii) Any certificate of need approved ambulatory surgical facility expanding the number of operating rooms shall be considered the construction, development or other establishment of a new ambulatory surgery facility. A certificate of need approved ambulatory surgical facility may not operate more than the number of operating rooms approved by the department identified on its certificate of need or approved in the department evaluation. However, expansion of the number of certificate of need approved operating rooms does not require certificate of need if approval if the expansion:

(A) Was completed without certificate of need approval prior to the effective date of these rules; or

(B) Received approval to begin construction from department of health construction review services prior to the effective date of these rules.

Stakeholder Engagement and Response

The proposed language was presented to stakeholders on August 14, 2015, and discussed further on September 16, 2015, and November 19, 2015. Entities represented were:

- Washington Ambulatory Surgery Center Association (WASCA)
- Swedish Providence
- Health Facilities Planning and Development (HFPD)
- Washington State Hospital Association (WSHA)
- ASC Compliance Solutions
- Proliance
- EVEIA Health Consulting;
- Providence Health Systems
- HealthTrends

Stakeholders provided comments and suggestions to Alternative B at the first two stakeholder meetings. Following review and consideration of written and oral stakeholder feedback, the department revised the proposed rule language to address stakeholder concerns. Specifically, the department addressed a request that the second sentence of Alternative B be removed to acknowledge facilities that may have expanded operating rooms when CoN approval was not required. The department also considered a suggestion to clarify that the rule applies to entities exceeding or planning to exceed the number of CoN approved operating rooms as of the effective date of the rule. Finally, the department considered that Alternative B failed to acknowledge operating rooms that may have been added pursuant to a health law judge ruling as opposed to a CoN approval. This resulted in Alternative C, which the department believes is the least burdensome of the three alternatives that meets the goals and objectives of the underlying statute chapter 70.38 RCW.

Alternative C was presented to stakeholders at the third stakeholder meeting. No new comments, suggestions or revisions to this language were offered.

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.