Significant Legislative Rule Analysis

Amended WAC 246-230-011 and new WAC 246-230-013
Severity matrix for fines related to acute care hospital enforcement implementing Second Substitute House Bill 1148 (chapter 61, laws of 2021)

August 9, 2022

SECTON 1:

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

In 2019, the Seattle Times published a three-part investigative report that shed light on patient safety issues in Washington's private psychiatric hospitals. One of the takeaways from the report was that the Department of Health (department) has had limited enforcement tools to address violations at these types of facilities. As a result, during the 2020 legislative session, the department put forth a request for legislation for psychiatric hospital enforcement, resulting in the introduction and passage of Substitute House Bill (SHB) 2426 (chapter 115, laws of 2020). The legislature expressed an interest in making the additional types of enforcement tools outlined in SHB 2426 applicable to acute care hospitals as well and passed Second Substitute House Bill (2SHB) 1148 in 2021.

The new law allows the department, under RCW 43.70.095, to assess a civil fine of up to ten thousand dollars per violation, not to exceed a total fine of one million dollars, on a licensed acute care hospital when the department determines the hospital has previously been subject to an enforcement action for the same or similar type of violation of the same statute or rule, or has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule, or when the hospital failed to correct noncompliance with a statute or rule by a date established or agreed to by the department.

2SHB 1148 requires the department to adopt rules establishing specific fine amounts in relation to:

- The severity of the noncompliance and at an adequate level to be a deterrent to future noncompliance; and
- The number of licensed beds and the operation size of the hospital.

The bill puts licensed beds into four categories:

- Up to 25 beds;
- 26 to 99 beds;
- 100 to 299 beds; and
- 300 beds or greater.

2SHB 1148 also directs the department to adopt a fee methodology that includes funding expenditures to implement the new enforcement tools. The department has determined that the fee methodology for initial and annual renewal of licensure in existing WAC 246-320-199 meets this requirement and therefore no new rulemaking is needed to implement this provision at this time.

Utilizing the ideas and concepts from the private psychiatric hospital rulemaking project as a springboard, the department conducted two workshops and solicited input from interested parties with the aim to create a fair yet binding regulation that addresses the intent of the bill.

The proposed rule sets these fine amounts and establishes a matrix of severity and process by which they will be applied.

SECTION 2:

Is a Significant Analysis required for this rule?

Yes, as defined in RCW 34.05.328(5)(c)(iii), this rule is a significant legislative rule that requires a significant analysis because it makes a significant change to a regulatory program. With the rule, the department will adopt provisions as delegated by the legislature in 2SHB 1148.

SECTION 3:

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

2SHB 1148 takes the additional enforcement tools introduced in SHB 2426 for psychiatric hospital enforcement and modifies them to be applicable to acute care hospitals, with the intention of having a consistent regulatory framework for facilities licensed through the department and ultimately protecting patients from risk of harm.

Section 2 of 2SHB 1148 instructs the department to adopt rules establishing one of the new enforcement tools – specific fine amounts in relation to the severity of the noncompliance and at an adequate level to be a deterrent to future noncompliance. The statute also instructs the department to consider the number of licensed beds and the operation size of the hospital when determining the fine amounts and provides four distinct categories of licensed beds. The goal of the rule is to clearly identify the amounts in relation to the severity of the noncompliance and to ensure that the fine amounts have an equitable financial impact on acute care hospitals.

To satisfy these requirements, the department developed a methodology that categorizes fine amounts according to the scope and severity of the violation, while also taking into consideration the operation size of the hospital and the number of licensed beds. This methodology is described in Section 6.

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.

There were no alternatives to adopting rules in order to implement the bill. The department was charged to do so. There were no alternatives to rulemaking that would allow the department to remain in alignment with the new statute.

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.

Description

The proposed rules establish a process for determining civil fines in relation to the severity of the noncompliance with established laws and rules by acute care hospitals. The proposed rules define and categorize levels of severity and scope for potential violations, as well as establish the fine amounts, which are similar to other established regulatory fines.

Cost

This rule does not require a licensed acute care hospital to implement any new requirements or make changes to their policies or procedures. As a result, there are no new costs associated with this rule.

No new costs will be imposed on licensed acute care hospitals unless they violate established laws and rules, and the department has determined:

- The licensed acute care hospital has previously been subject to an enforcement action for the same or similar type of violation of the same statute or rule, or
- The licensed acute care hospital has been given any previous statement of deficiency that included the same or similar type of violation of the same statute or rule, or
- The licensed acute care hospital failed to correct noncompliance with a statute or rule by a date established or agreed to by the department.

Benefit

The overarching benefit of this rule is to increase patient safety by ensuring that acute care hospitals, licensed in Washington state, comply with regulations. The rule will also help ensure, as required by the bill, that fine amounts serve as a deterrent to future noncompliance.

Determination

The department determines that the probable benefits of the rule outweigh the 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.

Due to the similarities between SHB 2426 and 2SHB 1148, the department leveraged the work that was completed last year for the private psychiatric hospital rulemaking project and used those concepts as a baseline for this rule.

In addition to this, this statute asks the department to consider the number of licensed beds and the operation size of the hospital when determining the fine amounts. The department believes that the intent of this component of the statute is to ensure that the fines have an equitable financial impact on hospitals, regardless of their size. The term "operation size" is not defined in statute, nor is there a standard dictionary definition that can be applied to acute care hospitals. The department worked with interested parties to consider ways to measure operation size. The consensus was to use fiscal data that hospitals already report to the department, since it is readily available.

The department examined hospital fiscal data for the years 2016, 2017, 2018 and 2019 and calculated the average operating budget (revenue plus costs) for each hospital size category provided in the statute (up to 25 beds; 26 to 99 beds; 100 to 299 beds; and 300 or more beds). Then the average operating budget for each of the first three size categories was compared to the average operating budget of the largest size category (300+ beds). The data showed that hospitals in the first two size categories had an average operating budget that was approximately 10% of the hospitals in the largest category and that hospitals in the third size category had an average operating budget that was approximately 30% of the hospitals in the largest category.

The department considered different options for incorporating this information into the methodology, including providing for a reduction for the hospitals in the 0-25, 26-99 and 100-299 categories, based on the above percentages. Ultimately, the department decided to set base fine amounts that were equal across hospital size category and to allow the maximum fine amount to scale with hospital size. The range of the fine amounts is as follows:

- 0-26 and 26-99 licensed beds: 100-110% of the base fine amount, corresponding to an average operating budget that is 10% of the largest hospitals.
- 100-299 licensed beds: 100-130% of the base fine amount, corresponding to an average operating budget that is 30% of the largest hospitals.
- 300+ licensed beds: 100-200% of the base fine amount.

This yielded the following tables, which are incorporated into the proposed rule language:

Table 1: 0-25 and 26-99 licensed beds

Fine Amounts in Relation to the Scope and Severity of the Violation			
	Severity		
Scope	Low	Moderate	High
Limited	$500-$550	$1,000 - $1,100	$2,000 - $2,200
Pattern	$1,000-$1,100	$2,000 - $2,200	$4,000-$4,400
Widespread	$1,500-$1,650	$3,000 - $3,300	$5,000-$5,500

Table 2: 100-299 licensed beds

Fine Amounts in Relation to the Scope and Severity of the Violation			
	Severity		
Scope	Low	Moderate	High

Fine Amounts in Relation to the Scope and Severity of the Violation			
	Severity		
Scope	Low	Moderate	High
Limited	$500-$650	$1,000 - $1,300	$2,000 - $2,600
Pattern	$1,000-$1,300	$2,000 - $2,600	$4,000-$5,200
Widespread	$1,500-$1,950	$3,000 - $3,900	$5,000-$6,500

Table 3: 300+ licensed beds

Fine Amounts in Relation to the Scope and Severity of the Violation			
	Severity		
Scope	Low	Moderate	High
Limited	$500-$1,000	$1,000 - $2,000	$2,000 - $4,000
Pattern	$1,000-$2,000	$2,000 - $4,000	$4,000-$8,000
Widespread	$1,500-$3,000	$3,000 - $6,000	$5,000-$10,000

To help ensure, as required by the bill, that fine amounts serve as a deterrent to future noncompliance, the department incorporated language into the rule that allows the department to assess a civil fine that is higher than the maximum fine amounts listed in the tables (not to exceed $10,000 per violation), if it is determined that the maximum amounts will not be a sufficient deterrent.

The department also shared and discussed alternative versions of the rule with partners and interested parties during two rules workshops. Workshop participants made recommendations on how to apply the term "harm" as it pertains to the severity of the violation, the number of survey cycles that should be considered when determining the lookback period for repeat violations, and the methodology for determining fine amounts.

- Potential vs actual harm: The draft language states that when determining the severity of the violation, the department will consider how the violation resulted, or could result, in harm and the impact of the actual potential or actual harm. While some workshop participants felt strongly that it is important to consider both potential and actual harm, others expressed concern that hospitals that admit higher acuity patients may be penalized under this structure. The intent of the law is to protect patients and prevent harm from occurring due to repeat violations. When determining the severity of the violation, the department believes that it is important to consider both whether harm did occur or had the potential to occur as a direct result of the repeat violation. Due to the fact that fines are limited to repeat violations and hospitals are given the opportunity to correct the initial violation before a fine would be considered, the department does not believe that hospitals that admit higher acuity patients will be disproportionately burdened by the proposed rule.

- Lookback period: The draft language states that when determining the scope of the violation, the department will consider the duration of time that has passed between repeat violations, up to a maximum of two prior hospital state survey cycles. The department heard from

several workshop participants that two survey cycles is too long, especially if surveys are delayed, which may result in opportunity for more repeat violations to be identified. One participant requested that the lookback period be limited to one survey cycle. The department recognizes that while hospitals may undergo significant organizational changes in a six-year period, this should not compromise patient safety and quality of care.

- Fine amounts: The statute requires the department to develop specific fine amounts that are based on the severity of the noncompliance and in an amount sufficient to be a deterrent to future noncompliance, while considering the number of licensed beds and the operation size of the hospital. The department presented several different methodologies to workshop participants and worked together to identify an option that would satisfy the requirements of the statute.

After strongly considering the comments and suggestions that it received from interested parties, the department concluded that the final proposed rule language achieves the best balance between protections for patient safety and minimizing potential hospital burden.

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 proposed rule does not require those to whom it applies to take an action that violates requirements of another 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 proposed rule does not impose more stringent performance requirements on private 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 proposed rule does not differ from any applicable federal regulation.

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.

During the development of SHB 2426, the department heard from interested parties that it would be prudent to align certain definitions in the statute with definitions used by the Joint Commission, so that if the accrediting body also took action on the hospital similar definitions would be applied. These definitions carried over into 2SHB 1148, which is beneficial as many acute care hospitals in Washington are accredited by the Joint Commission. Similarly, the department aligned this proposed rule language with the psychiatric hospital enforcement rule language, when practicable, so that the department can apply consistent regulatory approaches across licensed facility types.