

Significant Legislative Rule Analysis

Adding NEW Sections and Amending Chapter 246-455 WAC a Rule Concerning CHARS Data

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

The legislature passed Department of Health (department) request legislation, Engrossed Substitute Senate Bill 6265, in 2014, establishing conditions for release of information from the Comprehensive Hospital Abstract Reporting System (CHARS). The department proposed legislation to strengthen protections of patient health care information in CHARS. The bill requires the department to adopt rules to carry out its responsibilities under the law and to consider national standards when adopting rules.

A Bloomberg News reporter and Harvard University professor were able to identify patients in a data file that did not contain any direct patient identifiers, which raised questions about the ability to protect patient privacy under the existing law and rules.

The bill amended RCW 43.70.052 to require a signed data use agreement to obtain CHARS data. The bill prohibits all data users from re-disclosing the data file or attempting to identify a person in the dataset, except as authorized by the data use agreement.

The bill also distinguishes between “direct” patient identifiers and “indirect” patient identifiers (information that may reveal a patient’s identity when combined with other information).

The rules are needed to further define direct and indirect patient identifiers, clarify restrictions on use of the data, update definitions, and make housekeeping changes identified in the five-year rule review conducted by the department.

Is a Significant Analysis required for this rule?

Yes. The rule establishes the data elements included in data sets that will be released with a signed data use agreement. However, the department has determined that no significant analysis is required for the following portions of rule.

#	WAC Section	Section Title	Section Subject	Reason
1	246-455-010	Definitions	CHARS Definitions	This section makes housekeeping changes to the definitions to remove outdated or unnecessary language and to align the definitions with the law and rule
2	246-455-020	Reporting of data	Hospital	This section makes

		set information	reporting of CHARS data	housekeeping changes to remove outdated language and clarify existing language
3	246-455-070	Revisions of submitted data	Deadline for revising report of CHARS data	This section makes housekeeping changes to remove outdated references to another law
4	246-455-080	Security of Data	Requirements for securing data	This section makes housekeeping changes
5	246-455-090	Release of Data	Release of CHARS data	This section is repealed because it no longer applies or is now address in new section 085
6	246-455-100	Penalties for violation	Penalties regarding submission of data	This section is repealed because it references an outdated law

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

The general goal of the statute is to clarify conditions under which patient information in CHARS can be released. Specifically, the objectives of the law the rule implements are:

- Prohibiting release of direct and indirect patient identifiers to the public
- Allowing release of direct and indirect identifiers for use in research when approved by the Washington state institutional review board
- Allowing release of direct and indirect patient identifiers to federal, state and local government when a data use agreement has been signed
- Allowing release of indirect patient identifiers to any person, agency or researcher with a signed data use agreement
- Prohibiting recipients of indirect identifiers and public data sets from attempting to determine the identity of a person whose information is included in the data, or their families
- Prohibiting re-disclosure of data except as authorized in a data use agreement

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 proposed rule achieves the general goals and specific objectives of the statute by:

- Establishing types of data files, confidential, potentially identifiable and public, by specific identifier (i.e., patient name, race and ethnicity, five-digit zip code, age in years etc.)
- Determining when a combination of data elements may identify a patient (e.g., when a group of hospitalizations contains such a small cohort that one individual can easily be identified when linked with other information)

- Allowing options for creating a public data file to remove, aggregate, or anonymize the data

The law requires the department to adopt rules necessary to carry out the responsibilities of the law. The department would not be in compliance with the law if rules were not adopted.

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 purpose of these rules is to protect patient information and allow release of information only as permissible by law. It does not create any new costs for individuals not already incurred today by persons or organization to request data. Significant portions of the rule are analyzed below.

1. *New WAC 246-455-085- Data files – Release of data and data use agreements*

WAC 246-455-085 establishes the types of data files and how and when they can be released. The rule:

- Establishes confidential, potentially identifiable, and public data files by type of identifier
 - confidential data files contain direct identifiers, listed in the rule, and can only be released to government agencies with a data sharing agreement or to researchers with Washington state IRB approval
 - potentially identifiable data files contain indirect patient identifiers and can be released to any individual or organization with a data sharing agreement
 - public data files do not contain any direct or indirect data or may contain indirect patient identifiers by aggregating or anonymizing the data in the indirect patient identifier list and are freely available on the web
- Defines direct patient identifiers as:
 - patient name, social security number, medical record number, zip code, dates that include day, month and year, combinations of discharge and admission dates, and race and ethnicity.
- Defines indirect patient identifiers as any of the following when they create a group of ten or fewer hospitalizations:
 - Hospital or provider identifiers, five digit zip code, county, state and country of residence, dates that include month and year, admission and discharge hour, secondary diagnosis, procedure, present on admission, external cause of injury and payer codes, age in years, and race and ethnicity.
- Defines government agencies as Washington state boards, commissions, committees, departments, educational institutions, or other Washington state agencies created by or pursuant to statute (other than courts), Washington county or city agencies and US federal agencies
- Clearly restricts release of mental health and abortion data as required by other laws

Cost/Benefit Analysis:

There are no new costs associated with this rule. There is a current charge of \$50 to obtain data files from the department as allowed by law (RCW 43.70.052). The benefits of the rule are increased protection of patient data from CHARS, more options to allow the release of valuable

public health data while ensuring that individuals cannot be readily identified, and reinforced data user restrictions. It also creates clarity for data users and the public regarding what data elements are considered direct or indirect identifiers.

The benefit of the rule is increased protection of health care information. There are no costs directly related to the rule. Therefore the total probable benefits of the rule exceed the total probable costs.

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.

The department considered the following alternatives:

1. Remove all indirect patient identifiers from the public data file.

Although this option is still available when creating the file, not allowing other options in rule to create a public data file would have made the file an ineffective source of information.

2. Include age in years in the definition of direct identifiers:

Including age in years in the definition of direct identifier would have made it impossible to use the potentially identifiable data file for analysis of admissions based on age or groups of age. Instead, the rule allows release of age in years with a data use agreement and prohibits release of data by age in the public file if it creates a group of ten or fewer similar hospitalizations.

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 an action that violates requirements of federal or state law.

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. However, the law does allow government agencies, which includes public hospitals, to obtain data not accessible by private hospitals.

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. However, some of the data provided by hospitals in CHARS is considered confidential under HIPAA for hospitals. Once the data is submitted in CHARS, it is considered department data and the department is not a HIPAA-covered entity

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. As noted above, HIPAA applies to hospitals, but not to the department.