



PROPOSED RULE MAKING

CR-102 (June 2004)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Department of Health

- Preproposal Statement of Inquiry was filed as WSR 08-08-088 ; or
- Expedited Rule Making--Proposed notice was filed as WSR _ ; or
- Proposal is exempt under RCW 34.05.310(4).

- Original Notice
- Supplemental Notice to WSR
- Continuance of WSR

Title of rule and other identifying information: (Describe Subject)

Chapter 246-322 WAC Private Psychiatric and Alcoholism Hospitals - creating a new section (-260) for adverse health event and incident reporting system.

Hearing location(s): Department of Health
Point Plaza East, Room 139
310 Israel Road SE
Tumwater WA 98501

Date: 08/07/2008

Time: 9:30 AM

Submit written comments to:

Name: Alisa Harris
Address: PO Box 47850
Olympia WA 98504-7850
Website: <http://www3.doh.wa.gov/policyreview/>
fax (360) 236-2901 by (date) 08/07/2008

Assistance for persons with disabilities: Contact

Alisa Harris by 08/05/2008

TTY (800) 833-6388 or () 711

Date of intended adoption: 08/11/2008

(Note: This is NOT the effective date)

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

In 2006 the legislature passed 2SHB 2292 codified as chapter 70.56 RCW establishing the adverse health event and incident reporting system for 'medical facilities'. For the purposes of adverse event reporting, Psychiatric Hospitals are defined as a medical facility. The proposed rules include a list of reportable adverse events, how and when to report adverse events, the form and content of the root cause analysis and the corrective action plan. The intention of this legislation is to improve patient safety and decrease medical errors.

Reasons supporting proposal:

2SHB 2292 (chapter 70.56 RCW) requires the department to adopt in rule updates to the list of serious reportable events adopted by the national quality forums in 2002. Establishing the 2002 list in rule provides for a basis for future amendments. In addition, 2SHB 2292 requires the form and content of the root cause analysis and corrective action plan which are required in the event of the occurrence of adverse events to be adopted into rule.

Statutory authority for adoption:

Chapte 70.56 RCW

Statute being implemented:

Chapter 70.56 RCW

Is rule necessary because of a:

- Federal Law? Yes No
 - Federal Court Decision? Yes No
 - State Court Decision? Yes No
- If yes, CITATION:

DATE 07/01/08

NAME (type or print)

Mary C. Selecky

SIGNATURE

TITLE

Secretary

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: July 01, 2008

TIME: 1:04 PM

WSR 08-14-143

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:

N/A

Name of proponent: (person or organization)
Licensing

Department of Health, Office of Facilities and Services

- Private
 Public
 Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Byron Plan	310 Israel Road SE, Tumwater WA 98501	(360) 236-2905
Implementation....Byron Plan	310 Israel Road SE, Tumwater WA 98501	(360) 236-2905
Enforcement.....Steven Saxe	310 Israel Road SE, Tumwater WA 98501	(360) 236-2905

Has a small business economic impact statement been prepared under chapter 19.85 RCW?

Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone

fax

e-mail

No. Explain why no statement was prepared.

None of the facilities subject to this rule fall under the definition of a small business.

Is a cost-benefit analysis required under RCW 34.05.328?

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name:

Address:

phone

fax

e-mail

No: Please explain: This proposal is exempt from this requirement under RCW 34.05.328 5 (b) (v). The content of the rules are explicitly and specifically dictated by statute.

NEW SECTION

WAC 246-322-260 Adverse health event reporting. Psychiatric hospitals must:

(1) Notify the department whenever any of the following adverse events as defined by the National Quality Forum, *Serious Reportable Events in Health Care* occur:

1. Surgery performed on the wrong body part;
2. Surgery performed on the wrong patient;
3. Wrong surgical procedure performed on a patient;
4. Unintended retention of a foreign object in a patient after surgery or other procedure;
5. Intraoperative or immediately postoperative death in an ASA Class 1 patient;
6. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility;
7. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended;
8. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility;
9. Infant discharged to wrong person;
10. Patient death or serious disability associated with patient elopement (disappearance);
11. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a health care facility;
12. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration);
13. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products;
14. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the health care facility;
15. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a health care facility;
16. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia neonates;
17. Stage 3 or 4 pressure ulcers acquired after admission to a health care facility;
18. Patient death or serious disability due to spinal manipulative therapy;
19. Patient death or serious disability associated with electric shock or electric cardioversion while being cared for in a health care facility;
20. Any incident in which a line designed for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;
21. Patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility;
22. Patient death or serious disability associated with a fall while being cared for in a health care facility;
23. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility;

24. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider;
25. Abduction of a patient of any age;
26. Sexual assault on a patient within or on the grounds of a health care facility;
27. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a health care facility; and
28. Artificial insemination with the wrong donor sperm or egg;

(2) Notify the department within forty-eight hours of confirmation by the hospital when any adverse event has occurred. Until the internet-based reporting system is developed and available, notify the department using established procedures. The notice must include:

- (a) The hospital's name;
 - (b) The type of event identified in subsection (1) of this section; and
 - (c) The date the event occurred;
- (3) Conduct a root cause analysis of each adverse event following the procedures and methods of:
- (a) The joint commission;
 - (b) The department of Veterans Affairs National Center for Patient Safety; or
 - (c) Another nationally recognized root cause analysis methodology found acceptable by the department;
- (4) Create and implement a corrective action plan for each adverse event consistent with the findings of the root cause analysis. Each corrective action plan must include:
- (a) How each finding will be addressed and corrected;
 - (b) When each correction will be completed;
 - (c) Who is responsible to make the corrections;
 - (d) What action will be taken to prevent each finding from reoccurring; and
 - (e) A monitoring schedule for assessing the effectiveness of the corrective action plan including who is responsible for the monitoring schedule;
- (5) If a hospital determines there is no need to create a corrective action plan for a particular adverse event, provide a written explanation of the reasons for not creating a corrective action plan;
- (6) Once the internet-based reporting system is developed and available, complete and submit a report within forty-five days after confirming an adverse event has occurred.