LCB File No. R118-04

PROPOSED REGULATION OF THE HEALTH DIVISION OF THE DEPARTMENT OF HUMAN RESOURCES

CHAPTER 439 – ADMINISTRATION OF PUBLIC HEALTH

HEALTH AND SAFETY OF PATIENTS AT CERTAIN MEDICAL FACILITIES

SECTION 1. Definitions. (NRS 439.800) As used in This chapter, unless the context otherwise requires, the words and terms defined in NRS 439.809 to 439.890, inclusive, have the meanings ascribed to them in those sections.

SECTION 2. *Medical facility defined. Medical facility as defined in NRS 449.012, 449.0151.*

SECTION 3. Patient defined. Patient as defined in NRS 439.810.

SECTION 4. Patient safety officer defined. Patient safety officer as defined in NRS 439.870.

SECTION 5. Provider of health care defined. Provider of heath care as defined in NRS 439.820.

SECTION 6. Repository defined. Repository as defined in NRS 439.850.

SECTION 7. Sentinel event defined. Sentinel event defined in NRS 439.830.

SECTION 8. Reportable Sentinel Events defined.

- 1. Sentinel events that are reportable by a medical facility to the Health Division include any occurrence that meets any of the following criteria:
- (a) Event that has resulted in an unanticipated death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition:
- (1) A distinction is made between an adverse outcome that is primarily related to the natural course of the patient's illness or underlying condition not reported under the Sentinel Event reporting requirement and a death or major permanent loss of function that is associated with the treatment or lack of treatment of that condition, or otherwise not clearly and primarily related to the natural course of the patient's illness or underlying condition.
- (2) Major permanent loss of function means sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or life-style change.
- (3) When major permanent loss of function cannot be immediately determined, applicability of the reporting requirement is not established until either the patient is discharged with continued major loss of function, or two weeks have elapsed with persistent major loss of function, whichever occurs first; or
 - (b) Event was one of the following that occurred on the premise:
 - (1) Suicide of a patient in a setting where the patient receives around-the-clock care;

- (2) Unanticipated death of a full term infant;
- (3) Infant abduction;
- (4) Hemolytic transfusion reaction involving administration of blood or blood products having major group incompatibilities;
- (5) Rape defined as unconsented sexual contact involving a patient and another patient, staff member, or other perpetrator while being treated or on the premises of the medical facility, one or more of the following must be present to determine the applicability of the reporting rape requirement: any staff-witnessed sexual contact; sufficient clinical evidence obtained by the medical facility to support allegations of unconsented sexual contact; or admission by the perpetrator that sexual contact occurred;
- (6) Surgery on the wrong patient, regardless of the magnitude of the procedure or outcome;
- (7) Surgery on the wrong body part, regardless of the magnitude of the procedure or outcome;
 - (8) Wrong procedure performed, regardless of the magnitude of the outcome;
- (9) Assault, homicide or other crime resulting in patient death or major permanent loss of function;
- (10) Patient death, paralysis, coma or other major permanent loss of function associated with a medication error;
- (11) Patient fall that results in death or major permanent loss of function as a direct result of injuries sustained in the fall;
 - (12) Intrapartum maternal death related to the birth process;
- (12) Perinatal death unrelated to a congenital condition in an infant having a birth weight greater than 2,500 grams.

SECTION 9. *Mandatory reporting of sentinel events.*

- 1. Except as otherwise provided in subsection 2:
- (a) A person who is employed by a medical facility shall, within 24 hours after becoming aware of a sentinel event that occurred at the medical facility, notify the patient safety officer of the facility of the sentinel event; and
- (b) The patient safety officer shall, within 13 days after receiving notification pursuant to paragraph (a), report the date, the time and a brief description as specified in paragraph (c) to:
 - (1) The Health Division in a form as set forth in (d); and
- (2) The representative designated pursuant to NRS 439.855, if that person is different from the patient safety officer.
 - (c) The sentinel event report submitted to the Health Division will include:
- (1) The patient safety officer shall, within 13 days after receiving notification of a sentinel event, report the following information on the form administered by the Health Division:
 - (a) Facility name identified by code;
 - (b) Person reporting from the facility identified by name;
 - (c) Date of the event;
 - (d) Date and time the facility was notified of the event;
- (e) Date and time the Health Division was notified of the event, evidenced by fax date and time, postmark stamp date, email transmission date and time, or other date and time for another type of transmission;

- (f) Patient county of residence in Nevada;
- (g) Patient state or country of residence if not from Nevada;
- (h) Patient date of birth;
- (i) Patient gender;
- (j) Type of event, noting actual occurrence or potential occurrence;
- (k) Medical facility department involved in the event;
- (2) The following information is to be reported on the form administered by the Health Division, within 45 days after receiving notification of a sentinel event report;
- (a) Contributing factors to the event, specifying technical nature of the factors, patient related conditions manifesting as contributing factors, medical facility policies, procedures or situations manifesting as contributing factors, medical facility environmental conditions manifesting as contributing factors, medical facility staff behaviors or situations manifesting as contributing factors, and communication or documentation problems manifesting as contributing factors;
- (b) Corrective actions taken with respect to the event, including policy/procedure/process review, policy/procedure/process change or development, disciplinary actions/sanctions taken, environmental changes made, equipment modifications made; and education or retraining provided.
- (d) The Health Division will develop and distribute the reporting forms to all medical facilities, which must use these forms for reporting events.
- 2. If the patient safety officer of a medical facility personally discovers or becomes aware, in the absence of notification by another employee under 1.(a), of a sentinel event that occurred at the medical facility, the patient safety officer shall, within 14 days after discovering or becoming aware of the sentinel event, report the date, time and brief description as specified in section 1, paragraph (c) and (d) of the sentinel event to:
 - (a) The Health Division; and
- (b) The representative designated pursuant to NRS 439.855, if the person is different from the patient safety officer.

SECTION 10. Patient safety committee: Establishment; composition; meetings; duties; proceedings and records are privileged.

- 1. For those medical facilities having fewer than 25 employees and contractors, they will create a patient safety committee pursuant to subsection 1 composed of:
 - (a) The patient safety officer of the medical facility.
- (b) At least one medical and one nursing provider of health care who treat patients at the medical facility.
 - (c) The Chief Executive Officer or Chief Financial Officer of the medical facility.
 - (d) The patient safety committee shall meet at least quarterly.
- 2. The proceedings and records of a patient safety committee are subject to the same privilege and protection from discovery as the proceedings and records described in NRS 49.265.

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SMALL BUSINESS IMPACT STATEMENT

(Nevada Revised Statutes 439.800-890)

Proposed Amendment of Nevada Administrative Code (NAC) 439
Administration of Public Health

Health and Safety of Patients at Certain Medical Facilities

PROPOSED ADDITION TO REGULATIONS for the Health and Safety of Patients at Certain Medical Facilities has been generated by the Bureau of Health Planning and Statistics (BHP&S).

Background:

When Assembly Bill 1 (AB1) was passed during the 2002 18th Special Legislative Session, mandatory reporting of sentinel events was incorporated into Nevada Revised Statute (NRS) 439.800-890. Mandatory reporting begins January 1, 2005. The State of Nevada Health Division is responsible for maintaining the Sentinel Events Registry (NRS 439.840), which will be done by the Bureau of Health Planning and Statistics. The adoption of this regulation is necessary to carry out the provisions of NRS 439.800-890, and the proposed amendment includes the following components: 1) the definition of reportable sentinel events; 2) the definition of the process for the mandatory reporting of sentinel events; and 3) the requirements for patient safety committees.

BHP&S has determined that the adoption of this regulation should not create an economic impact on medical facilities who are required to report sentinel events and who also qualify as small business as defined in Nevada Revised Statutes (NRS) 233B as a "business conducted for profit which employs fewer than 150 full-time or part-time employees". This small business impact statement complies with the requirements of NRS 233B.0609.

1. A description of the manner in which comment was solicited from affected small businesses, a summary, and an explanation of the manner in which other interested parties may obtain a copy of the summary.

Provider comments were solicited during the draft proposal process by the Bureau of Health Planning and Statistics, and each qualifying provider received a Small Business Impact Questionnaire.

Copies of the summary of these questionnaires are available from the office of the Bureau of Health Planning and Statistics, 505 East King Street, Room 102, Carson City, Nevada 89701-4749. (775) 684-4218.

2. The estimated economic effect of the proposed regulation on the small business which it is to regulate including, without limitation, both adverse and beneficial effects.

The responses from the surveyed providers were unanimous that there should be no economic effects, adverse or beneficial, to their small business.

3. A description of the methods the agency considered to reduce the impact of the imposed regulation on small business and a statement regarding whether the agency actually used any of those methods.

BHP&S realized the best course to reduce the impact of the proposed regulation on small business was to involve the health care industry in the implementation of NRS 439.800-890. The Nevada Hospital Association and the State of Nevada Health Division have partnered, under the auspices of the Nevada Hospital Association, to form the Nevada Sentinel Events Registry Steering Committee and the Nevada Sentinel Events Registry Facility Work Group to address the mandatory reporting of sentinel events. They have been working diligently to meet the requirements set forth in AB 1.

4. The estimated cost to the agency for enforcement of proposed regulations.

The approximate cost to the agency is \$150,000.

5. If the proposed regulation provides a new fee or increases an existing fee, the total annual amount the agency expects to collect and the manner in which the money will be used.

There is no fee or increased fee associated with the proposed regulation.

6. If the proposed regulation includes provisions which duplicate or are more stringent than federal, state or local standards regulating the same activity, an explanation of why such duplicative or more stringent provisions are necessary.

This regulation does not represent duplication on local, state or federal levels. The State of Nevada Health Division is responsible for generating regulations governing the mandatory reporting of sentinel events pursuant to NRS 439.840. There is no equivalent responsibility on the local or federal level

Summary of Responses:

There were seven responses received from providers who qualified as a small business as defined in NRS 233B. All seven respondents replied "No" to all of the following questions:

1) Will the regulation have an adverse economic effect upon your business?, 2) Will the regulation have any beneficial effect on your business?, 3) Do you anticipate any indirect adverse effects upon your business?, and 4) Do you anticipate any indirect beneficial effects upon your business?.