

**ADOPTED REGULATION OF THE ADMINISTRATOR OF THE  
HEALTH DIVISION OF THE DEPARTMENT OF  
HUMAN RESOURCES**

**LCB File No. R118-04**

Effective November 4, 2004

EXPLANATION – Matter in *italics* is new; matter in brackets ~~[omitted material]~~ is material to be omitted.

AUTHORITY: §§1-8, NRS 439.890; §9, NRS 439.835 and 439.890; §10, NRS 439.875 and 439.890.

A REGULATION relating to public health; defining certain terms relating to sentinel events; setting forth the requirements for reports of sentinel events; establishing the composition of patient safety committees at certain medical facilities; and providing other matters properly relating thereto.

**Section 1.** Chapter 439 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 10, inclusive, of this regulation.

**Sec. 2.** *As used in sections 2 to 10, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 3 to 8, inclusive, of this regulation, have the meanings ascribed to them in those sections.*

**Sec. 3.** *“Division” means the Health Division of the Department of Human Resources.*

**Sec. 4.** *“Medical facility” has the meaning ascribed to it in NRS 439.805.*

**Sec. 5.** *“Patient” has the meaning ascribed to it in NRS 439.810.*

**Sec. 6.** *“Patient safety officer” has the meaning ascribed to it in NRS 439.815.*

**Sec. 7.** *“Provider of health care” has the meaning ascribed to it in NRS 439.820.*

**Sec. 8.** *“Sentinel event” has the meaning ascribed to it in NRS 439.830.*

**Sec. 9. 1. A report submitted pursuant to NRS 439.835 must be submitted on the form prescribed pursuant to subsection 4 and must include:**

**(a) The unique identification code assigned to the medical facility by the Division pursuant to subsection 5;**

**(b) The name of the person who is making the report;**

**(c) The date on which the sentinel event occurred;**

**(d) The date and time that the medical facility was notified of the occurrence of the sentinel event;**

**(e) If the patient resides in this State, the county in which the patient resides;**

**(f) If the patient does not reside in this State, the state or country in which the patient resides;**

**(g) The date of birth of the patient;**

**(h) The gender of the patient;**

**(i) A description of the sentinel event; and**

**(j) The department of the medical facility at which the sentinel event occurred.**

**2. Within 45 days after receiving notification or becoming aware of the occurrence of a sentinel event pursuant to subsection 1 or 2 of NRS 439.835, the patient safety officer of the medical facility in which the sentinel event occurred must submit a second report to the Division. A report required by this subsection must be submitted on the form prescribed pursuant to subsection 4 and must include:**

**(a) The factors that contributed to the sentinel event, including, without limitation:**

**(1) Any medical or other condition of the patient;**

**(2) Any policy, procedure or process of the medical facility;**

- (3) Any environmental condition of the medical facility;*
  - (4) Any behavior of a member of the staff of the medical facility;*
  - (5) Any situation present at the medical facility; and*
  - (6) Any problem involving communication or documentation at the medical facility.*
- (b) The corrective actions, if any, taken by the medical facility to address the factors that contributed to the sentinel event, including, without limitation:*
- (1) A review of the policies, procedures or processes of the medical facility;*
  - (2) Any change or development of the policies, procedures or processes of the medical facility;*
  - (3) Any disciplinary actions taken against a member of the staff of the medical facility by the medical facility;*
  - (4) Any environmental or equipment changes made in the medical facility; and*
  - (5) Any education or retraining provided to the staff of the medical facility.*
- 3. A report submitted pursuant to subsection 1 must indicate the date and time that the report was submitted to the Division. Proof satisfactory to the Division of the date and time that a report was submitted includes:*
- (a) The postmark on the package in which the report was submitted to the Division;*
  - (b) The time stamp created by a facsimile machine used to transmit the report to the Division;*
  - (c) The electronic time stamp created by a program of electronic mail used to transmit the report to the Division; and*
  - (d) Any other evidence acceptable to the Division, as indicated on the form created by the Division pursuant to subsection 4.*

*4. The Division will develop a form for each report required by subsection 1 or 2. The Division will distribute copies of the forms created pursuant to this subsection to each medical facility in this State.*

*5. The Division will assign a unique identification code to each medical facility in this State, to be used on the reports required by subsections 1 and 2.*

**Sec. 10.** *1. A medical facility that has fewer than 25 employees and contractors shall establish a patient safety committee composed of:*

*(a) The patient safety officer of the medical facility;*

*(b) At least two providers of health care who treat patients at the medical facility, including, without limitation, one member of the medical staff and one member of the nursing staff of the medical facility; and*

*(c) The chief executive officer or chief financial officer of the medical facility.*

*2. A patient safety committee established pursuant to this section must meet at least once every calendar quarter.*

**NOTICE OF ADOPTION OF PROPOSED REGULATION**  
**LCB File No. R118-04**

The Health Division of the Department of Human Resources adopted regulations assigned LCB File No. R118-04 which pertain to chapter 439 of the Nevada Administrative Code on September 24, 2004.

**Notice date:** 8/20/2004  
**Hearing date:** 9/24/2004

**Date of adoption by agency:** 9/24/2004  
**Filing date:** 11/4/2004

**INFORMATIONAL STATEMENT**

**1. DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED, SUMMARY OF PUBLIC RESPONSE, AND AN EXPLANATION OF HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.**

A Small Business Impact Questionnaire was mailed to Hospitals, Inpatient Psychiatric Centers, Inpatient Rehabilitation Hospitals, Surgical Centers for Ambulatory Patients, and Independent Centers for Emergency Medical Care on April 15, 2004. Attachment A is the Small Business Impact Statement Questionnaire. Attachment B is a copy of the small business impact summary.

Notice of public workshops held on May 6, 2004, in Reno and on May 7, 2004, in Las Vegas was published in the Reno Gazette Journal and Las Vegas Review-Journal on April 16, 2004. Notices of the public workshops and proposed regulations were faxed or mailed to the Nevada State Library, all county main public libraries in Nevada, all Hospitals, all Inpatient Psychiatric Centers, all Inpatient Rehabilitation Hospitals, all Surgical Centers for Ambulatory Patients, and all Independent Centers for Emergency Medical Care on April 15, 2004. The small business impact summary was available at both workshops.

Notice of public hearing regarding the intent of the Administrator of the Nevada State Health Division to adopt amendments was published in the Las Vegas Review Journal and Reno Gazette Journal on August 20, 2004. Notices of public hearing, and proposed regulations were faxed or mailed to the Nevada State Library, all county main public libraries in Nevada, all Hospitals, all Inpatient Psychiatric Centers, all Inpatient Rehabilitation Hospitals, all Surgical Centers for Ambulatory Patients, and all Independent Centers for Emergency Medical Care on August 19, 2004.

There were no public comments or testimony provided during the workshops.

Copies of the minutes from the workshop and the hearing may be obtained by calling the Bureau of Health Planning and Statistics at (775) 684-4169.

**2. THE NUMBER OF PERSONS WHO:**

(A) ATTENDED THE HEARING;

Eight (8) people attended the September 24, 2004 public hearing.

**(B) TESTIFIED AT EACH HEARING; AND**

No one in attendance testified on the Health and Safety of Patients at Certain Medical Facilities.

**(C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.**

No written testimony was submitted to the agency.

**3. A DESCRIPTION OF HOW COMMENT WAS SOLICITED FROM AFFECTED BUSINESSES, A SUMMARY OF THEIR RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY**

Comment was solicited from affected or potentially affected businesses by mailing appropriate facilities and all interested parties the proposed regulations, a small business impact questionnaire, a copy of the small business impact summary, and the notices for the workshops and public hearing. Copies of the workshop minutes may be obtained by calling the Bureau of Health Planning and Statistics at (775) 684-4169.

**4. IF THE REGULATION WAS ADOPTED WITHOUT CHANGING ANY PART OF THE PROPOSED REGULATION, A SUMMARY OF THE REASONS FOR ADOPTING THE REGULATION WITHOUT CHANGE.**

No testimony was received in opposition to the proposed regulations or which suggested changes to the proposed regulation.

The Administrator for the Nevada State Health Division adopted the proposed amendments to NAC 439, "Health and Safety of Patients at Certain Medical Facilities," LCB File No. R118-04, as presented.

**5. THE ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH IT IS TO REGULATE AND ON THE PUBLIC. THESE MUST BE STATED SEPARATELY, AND IN EACH CASE MUST INCLUDE:**

**(A) BOTH ADVERSE AND BENEFICIAL EFFECTS; AND**

Anticipated effects on the businesses which NAC 439 regulates:

Adverse: None

Beneficial: Impose requirements in accordance with NRS 439 and reporting of Sentinel Events.

Anticipated effects on the public:

Adverse: None

Beneficial: Impose requirements in accordance with NRS 439 and reporting of Sentinel Events.

(B) BOTH IMMEDIATE AND LONG TERM EFFECTS.

Anticipated effects on the businesses which NAC 439 regulates:

Immediate: The proposed regulations would become effective upon filing with the Secretary of State after adoption by the Administrator of the Nevada State Health Division. Those regulations related to the mandatory reporting of sentinel events licensure are anticipated to become effective in the Fall of 2004 for facilities that are required to report sentinel events beginning January 1, 2005.

Long-term: On-going implementation

Anticipated effects on the public:

Immediate: Impose requirements in accordance with NRS 439 and reporting of Sentinel Events.

Long-term: Impose requirements in accordance with NRS 439 and reporting of Sentinel Events.

6. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

There is no anticipated additional cost to the agency for the enforcement of the proposed regulation changes.

7. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH THE PROPOSED REGULATION OVERLAPS OR DUPLICATES AND A STATEMENT EXPLAINING WHY THE DUPLICATION OR OVERLAPPING IS NECESSARY. IF THE REGULATION OVERLAPS OR DUPLICATES A FEDERAL REGULATION, NAME THE REGULATING FEDERAL AGENCY.

The proposed regulations do not overlap any other Nevada state regulations. There is no duplication of federal regulations and no matching counterpart in the code of federal regulations.

8. IF THE REGULATION INCLUDES PROVISION WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISION.

None

9. IF THE 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.

The amendments do not establish any new fees or increase any existing fees.



EXHIBIT A

Small Business Impact Questionnaire

The following questions pertain to how the changes in the Nevada Administrative Code presented in the enclosure will affect your business. If it is determined that the proposed regulation is likely to impose a direct and significant economic burden upon a small business; or directly restrict the formation, operation or expansion of a small business; then the agency will take any or all of the following actions:

1. Insofar as practicable, consult with owners and officers of affected small businesses,
2. Consider methods to reduce the impact of the proposed regulation, and
3. Prepare a small business impact statement and make copies of the statement available to the public at the workshop conducted and the public hearing held pursuant to NRS 233B.061.

Please answer the questions that apply and add any qualifying remarks that may help us understand your position. Mail or FAX your completed form to:

Tina Perry, Health Resource Analyst III  
Bureau of Health Planning & Statistics  
505 E King Street, Room 102  
Carson City, NV 89701

FAX (775) 684-4156

Name \_\_\_\_\_

Organization \_\_\_\_\_

Date \_\_\_\_\_

NRS 233B.0382 "Small business" defined. "Small business" means a business conducted for profit which employs fewer than 150 full-time or part-time employees.

1. How many employees are currently employed by your business? \_\_\_\_\_

Your comments will be accepted and reviewed as part of the Small Business Impact process even if your facility does not meet the statutory definition of a small business as described above. We encourage you to submit your comments. Please FAX the questionnaire to the above address.

2. Will a specific regulation have an adverse economic effect upon your business?

Yes \_\_\_\_\_ No \_\_\_\_\_  
and explain the impact.

Explain: Please list each regulation

3. Will the regulation(s) have a beneficial effect upon your business?

Yes \_\_\_\_\_ No \_\_\_\_\_

Explain:

4. Do you anticipate any indirect adverse effects upon your business?

Yes \_\_\_\_\_ No \_\_\_\_\_

Explain:

5. Do you anticipate any beneficial effects upon your business?

Yes \_\_\_\_\_ No \_\_\_\_\_

Explain:

## EXHIBIT B

### 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?.

