PROPOSED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R044-10

July 12, 2010

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

AUTHORITY: §§1-4 and 12, NRS 439.890; §§5 and 13, NRS 439.835 and 439.890; §6, NRS 439.837, 439.841 and 439.890; §§7-11, NRS 439.847 and 439.890.

A REGULATION relating to public health; revising provisions relating to reports of sentinel events; establishing reporting requirements for certain patient safety information and certain other health information by 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 11, inclusive, of this regulation.

Sec. 2. ***"Facility-acquired infection" has the meaning ascribed to it in NRS 439.802.***

Sec. 3. ***"National Healthcare Safety Network" means the secure, Internet-based surveillance system established by the Division of Healthcare Quality Promotion of the Centers for Disease Control and Prevention of the United States Department of Health and Human Services that integrates patient and health care personnel safety surveillance systems.***

Sec. 4. ***"Physician" means:***

1. A physician licensed pursuant to chapter 630 of NRS;

2. A homeopathic physician licensed pursuant to chapter 630A of NRS;

3. An osteopathic physician licensed pursuant to chapter 633 of NRS;

4. A chiropractic physician licensed pursuant to chapter 634 of NRS; or

5. A podiatric physician licensed pursuant to chapter 635 of NRS.

Sec. 5. ***1. If a medical facility that receives a patient who was transferred or discharged from another medical facility believes that a sentinel event affecting the patient occurred at the other medical facility, the medical facility that received the patient shall report the sentinel event to the facility from which the patient was transferred or discharged.***

2. A medical facility that is informed of a sentinel event pursuant to subsection 1 shall report the sentinel event pursuant to NRS 439.835 and NAC 439.900 to 439.920, inclusive, and sections 2 to 11, inclusive, of this regulation.

Sec. 6. ***1. Within 45 days after reporting a sentinel event pursuant to NRS 439.835, the medical facility shall conduct an investigation of the causes or contributing factors, or both, of the sentinel event.***

2. The investigation conducted pursuant to this section must:

(a) Determine whether changes in the policies, procedures or processes of the medical facility are necessary to prevent a subsequent sentinel event under similar circumstances.

(b) Follow a nationally recognized methodology for conducting an analysis of the root cause of the sentinel event, including, without limitation, the methodology prescribed by:

(1) The Joint Commission; or

(2) The United States Department of Veterans Affairs National Center for Patient Safety.

(c) Be provided to the Health Division upon request.

3. Except as otherwise provided in subsection 4, a medical facility shall, after conducting an investigation pursuant to this section, develop and implement a plan to remedy the causes or contributing factors, or both, of the sentinel event. The plan must:

(a) State how each finding of the investigation will be addressed and, if necessary, corrected by the medical facility;

(b) Identify the changes and corrective actions that will be implemented by the medical facility to reduce risk to patients or provide an explanation for not implementing any changes or corrective actions;

(c) Provide the title of the person responsible for implementing each change and corrective action identified in plan;

(d) Provide a timeline for implementing the plan, including, without limitation, when each change or corrective action will be implemented by the medical facility;

(e) Provide for an evaluation of the effectiveness of the plan and a method for making revisions to the plan based on the evaluation;

(f) Establish a schedule for monitoring and assessing the continued effectiveness of the plan; and

(g) Provide the title of the person who is responsible for monitoring the overall plan.

4. If, after conducting an investigation pursuant to this section, a medical facility determines that a plan to remedy the causes or contributing factors, or both, of the sentinel event is not necessary, the medical facility shall prepare a written statement documenting the reasons for making such a determination.

5. Except as otherwise provided in this section and NRS 239.0115, information provided to the Health Division relating to the plan developed pursuant to subsection 3 or the statement prepared pursuant to subsection 4 and any additional information requested by the Health Division is confidential, not subject to subpoena or discovery and not subject to inspection by the general public.

Sec. 7. ***For purposes of subsection 1 of NRS 439.847, to determine whether a medical facility provides medical services and care to an average of 25 or more patients during each business day in the immediately preceding calendar year, the Health Division shall:***

1. For a hospital described in NRS 439.805, divide the total number of inpatients admitted to the hospital during the preceding calendar year by 365.

2. For a medical facility other than a hospital, divide the total number of patients seen by the medical facility in the immediately preceding calendar year by the total number of days on which the medical facility was open for business during that calendar year.

Sec. 8. ***1. Each medical facility that participates in the National Healthcare Safety Network shall:***

(a) Subscribe to the National Healthcare Safety Network user group designated by the Health Division.

(b) Comply with the requirements of the Centers for Disease Control and Prevention of the United States Department of Health and Human Services for enrolling and maintaining enrollment in the National Healthcare Safety Network.

(c) Comply with all definitions, methods, requirements and procedures established by the Centers for Disease Control and Prevention when collecting and submitting data to the National Healthcare Safety Network.

(d) Designate a person employed by the medical facility to act as the facility administrator for the National Healthcare Safety Network.

(e) Designate the persons at the medical facility who are authorized to access the National Healthcare Safety Network, if the medical facility determines that such access is necessary.

(f) Complete all training required by the Centers for Disease Control and Prevention for participation in the National Healthcare Safety Network and ensure that the facility administrator designated pursuant to paragraph (d) and each person who is authorized to access the National Healthcare Safety Network pursuant to paragraph (e) have been properly trained.

2. The person designated as the facility administrator for the National Healthcare Safety Network pursuant to paragraph (d) of subsection 1 is the person at the medical facility who is primarily responsible for accessing the National Healthcare Safety Network and submitting the required data to the National Healthcare Safety Network. The facility administrator must:

(a) Have authority to access all data of the medical facility that is required for submitting information to the National Healthcare Safety Network;

(b) Be able to certify authorized users who have been designated pursuant to paragraph (e) of subsection 1 by the medical facility to access the National Healthcare Safety Network and assist those persons in accessing the National Healthcare Safety Network; and

(c) Be responsible for accepting official documents and correspondence from the Centers for Disease Control and Prevention and the administrator of the National Healthcare Safety Network.

Sec. 9. *1. Each hospital described in NRS 439.805 that is required to participate in the National Healthcare Safety Network shall:*

(a) Submit data to the National Healthcare Safety Network relating to all central line-associated bloodstream infection events.

(b) Commencing not later than February 1, 2011, submit data to the National Healthcare Safety Network relating to the nosocomial methicillin-resistant Staphylococcus aureus

infection rate of patients for each patient care location within the hospital that has been identified by the Centers for Disease Control and Prevention.

(c) Commencing not later than February 1, 2011, submit to the National Healthcare Safety Network the incident rate of hospital-onset methicillin-resistant Staphylococcus aureus bloodstream infections, which must be based on clinical cultures, for each patient care location within the hospital that has been identified by the Centers for Disease Control and Prevention.

(d) Commencing not later than February 1, 2011, implement the Antimicrobial Use and Resistance Option within the Medication-Associated Module of the Patient Safety Component of the National Healthcare Safety Network.

(e) Commencing not later than June 1, 2011, submit data to the National Healthcare Safety Network concerning surgical site infections relating to a:

(1) Coronary artery bypass graft with both chest and donor site incisions;

(2) Hip prosthesis;

(3) Knee prosthesis; and

(4) Laminectomy.

➥ Each hospital shall continue to report the information required pursuant to this subsection to the National Healthcare Safety Network at the times and in the manner prescribed by the National Healthcare Safety Network for submission of that information.

2. Each surgical center for ambulatory patients described in NRS 439.805 that is required to participate in the National Healthcare Safety Network shall submit data to the National Healthcare Safety Network concerning surgical site infections relating to a:

(a) Gallbladder surgery;

(b) Open reduction of a fracture;

(c) Herniorrhaphy; and

(d) Breast surgery.

➥ Each surgical center for ambulatory patients shall continue to report the information required pursuant to this subsection to the National Healthcare Safety Network at the times and in the manner prescribed by the National Healthcare Safety Network for submission of that information.

3. Each independent center for emergency medical care described in NRS 439.805 that is required to participate in the National Healthcare Safety Network shall submit data to the National Healthcare Safety Network concerning the influenza vaccination rate of the health care personnel of the center. Each independent center for emergency medical care shall continue to report the information required pursuant to this subsection to the National Healthcare Safety Network at the times and in the manner prescribed by the National Healthcare Safety Network for submission of that information.

4. Each obstetric center described in NRS 439.805 that is required to participate in the National Healthcare Safety Network shall submit data to the National Healthcare Safety Network concerning the influenza vaccination rate of the health care personnel of the center. Each obstetric center shall continue to report the information required pursuant to this subsection to the National Healthcare Safety Network at the times and in the manner prescribed by the National Healthcare Safety Network for submission of that information.

5. A physician who performs a medical procedure at a medical facility that is required to report to the National Healthcare Safety Network shall report to the medical facility any

facility-acquired infection which is diagnosed at a follow-up examination of the patient and which resulted from the medical procedure performed at the medical facility.

6. A medical facility shall report all confirmed and all suspected instances of a facility-acquired infection acquired at another medical facility to the medical facility in which the infection was acquired. The medical facility which reports a confirmed or suspected instance of a facility-acquired infection pursuant to this subsection shall keep a record of that report for not less than 3 years after making such report.

Sec. 10. *1. Except as otherwise provided in this section and NRS 239.0115, information provided to the Health Division through the National Healthcare Safety Network and any additional information requested by the Health Division is confidential, not subject to subpoena or discovery and not subject to inspection by the general public.*

2. The Health Division shall annually prepare and post on the Internet website maintained by the Health Division a report of aggregated data provided to the National Healthcare Safety Network.

3. The Health Division shall:

(a) Ensure that the name and other personally identifying information regarding each patient are kept confidential when preparing the report.

(b) Adhere to standard methods of suppressing protected health information and reporting to ensure that the identity of a patient is not revealed and to preserve patient confidentiality.

4. The Health Division may, at such times as it deems necessary, audit a medical facility that participates in the National Healthcare Safety Network to ensure the accuracy of information submitted by the medical facility, including, without limitation, data relating to facility-acquired infections, health care records and tests.

Sec. 11. ***1. If a medical facility participates in the National Healthcare Safety Network, the chief executive officer of the medical facility, or the officer's designee, shall, on or before March 1 of each year, submit to the Health Division a signed statement certifying that the medical facility has processes in place to ensure that the data relating to facility-acquired infections submitted to the National Healthcare Safety Network is accurate and meets the requirements of NAC 439.900 to 439.920, inclusive, and sections 2 to 11, inclusive, of this regulation.***

2. The signed statement required by subsection 1 must be mailed to the Bureau of Health Care Quality and Compliance, 1550 East College Parkway, Suite 158, Carson City, Nevada 89706.

Sec. 12. NAC 439.902 is hereby amended to read as follows:

439.902 ~~[~~ "~~]~~ ***"Health*** Division" means the Health Division of the Department of Health and Human Services.

Sec. 13. NAC 439.915 is hereby amended to read as follows:

439.915 1. A report submitted pursuant to NRS 439.835 must be submitted ~~[on the form]~~ ***in the format*** prescribed pursuant to subsection 4 and must include ~~[:]~~ ***, without limitation:***

(a) The unique identification code assigned to the medical facility by the ***Health*** 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 ***Health*** Division. A report required by this subsection must be submitted ~~[on the form]~~ ***in the format*** prescribed pursuant to subsection 4 and must include ~~[:]~~ ***, without limitation:***

(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, ***identified pursuant to section 6 of this regulation that will be*** 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 ~~[.]~~ ***;***

(6) The date by which each corrective action will be completed; and

(7) The title of the person who is responsible for overseeing each corrective action.

(c) A copy of the plan to remedy the causes or contributing factors, or both, of the sentinel event developed pursuant to subsection 3 of section 6 of this regulation or the statement prepared pursuant to subsection 4 of that section.

3. A report submitted pursuant to subsection 1 must indicate the date and time that the report was submitted to the ***Health*** Division. Proof satisfactory to the ***Health*** 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 ***Health*** Division;

(b) The time stamp created by a facsimile machine used to transmit the report to the ***Health*** Division;

(c) The electronic time stamp created by a program of electronic mail used to transmit the report to the ***Health*** Division; and

(d) Any other evidence acceptable to the ***Health*** Division, as indicated on the form created by the ***Health*** Division pursuant to subsection 4.

4. The ***Health*** Division ~~[will]~~ ***shall*** develop ~~[a form]~~ ***the format*** for each report required by subsection 1 or 2 ~~[.]~~ ***, which must require, without limitation, the reporting of information relating to events on the list of serious reportable events contained in the most recent version of "Serious Reportable Events in Healthcare," issued by the National Quality Forum, which is***

hereby adopted by reference. The ***Health*** Division ~~[will]~~ ***shall*** distribute copies of the forms created pursuant to this subsection to each medical facility in this State. ***The Health Division shall notify medical facilities that an update to a form is available within 30 days after making a change to a form.***

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

6. The most recent edition of "Serious Reportable Events in Healthcare," which is adopted by reference pursuant to subsection 4, may be obtained from the National Quality Forum, 601 13th Street NW, Suite 500 North, Washington, D.C. 20005 or on the Internet at http://www.qualityforum.org/Publications.aspx. If the State Board of Health determines that a revision is not suitable for this State, the Board will:

(a) Hold a public hearing to review its determination within 6 months after the date of the publication of the revision; and

(b) Give notice of that hearing.

➥ If, after the hearing, the Board does not revise its determination, the Board will give notice within 30 days after the hearing that the revision is not suitable for this State. If the Board does not give such notice, the revision becomes part of the publication adopted by reference pursuant to subsection 4.