PROPOSED REGULATION OF THE STATE BOARD OF HEALTH

LCB File No. R044-10

These regulations are being proposed in accordance with Senate Bill 319 of the 2009 legislative session.

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

Chapter 439 of NAC is hereby amended by adding thereto the provisions set forth as sections 10 to 15, inclusive, of this regulation.

NAC 439.900 Definitions. (NRS 439.890**)** As used in NAC 439.900 to 439.920, inclusive, unless the context otherwise requires, the words and terms defined in NAC 439.902 to 439.912, inclusive, have the meanings ascribed to them in those sections. (Added to NAC by Health Div. by R118-04, eff. 11-4-2004)

NAC 439.902 "Division" defined. (NRS 439.890**)** "Division" means the Health Division of the Department of Health and Human Services. (Added to NAC by Health Div. by R118-04, eff. 11-4-2004)

Section 1. ***"Facility-acquired infection" defined. "Facility-acquired infection" has the meaning ascribed to it in NRS 439.802.***

NAC 439.904 "Medical facility" defined. (NRS 439.890**)** "Medical facility" has the meaning ascribed to it in NRS 439.805. (Added to NAC by Health Div. by R118-04, eff. 11-4-2004)

Sec 2. ***"NHSN" defined. NHSN means the secure, Internet-based surveillance system established by the Division of Healthcare Quality Promotion of the Centers for Disease Control and Prevention (CDC) of the United States Department of Health and Human Services that integrates patient and health care personnel safety surveillance systems until a derivative or successor system is adopted by CDC.***

Sec 3. ***"NHSN Facility Administrator" defined. "NHSN Facility Administrator" means the person at a medical facility assigned to have:***

(a) All rights to the medical facility's data for reporting to NHSN;

(b) The ability to create authorized users and confer rights to them in NHSN;

(c) The ability to nominate groups with which the medical facility wants to share some or all of its data reported in NHSN; and

(d) The responsibility for accepting official documents regarding NHSN.

Sec 4. ***"NHSN Authorized User" defined. "NHSN Authorized User" means any person the NHSN Facility Administrator designates through NHSN to submit information to, receive information from, or access or review information contained in NHSN, on behalf of his or her health care facility.***

NAC 439.906 "Patient" defined. (NRS 439.890**)** "Patient" has the meaning ascribed to it in NRS 439.810. (Added to NAC by Health Div. by R118-04, eff. 11-4-2004)

NAC 439.908 "Patient safety officer" defined. (NRS 439.890**)** "Patient safety officer" has the meaning ascribed to it in NRS 439.815. (Added to NAC by Health Div. by R118-04, eff. 11-4-2004)

Sec 5. ***"Physician" defined. "Physician" means a person who is licensed to practice medicine pursuant to chapter 630 of NRS, chiropractic physicians licensed pursuant to chapter 634 of NRS, homeopathic physicians licensed pursuant to chapter 630A of NRS, a person who is licensed to practice osteopathic medicine pursuant to chapter 633 of NRS or to practice podiatric medicine pursuant to chapter 635 of NRS.***

NAC 439.910 "Provider of health care" defined. (NRS 439.890**)** "Provider of health care" has the meaning ascribed to it in NRS 439.820. (Added to NAC by Health Div. by R118-04, eff. 11-4-2004)

NAC 439.912 "Sentinel event" defined. (NRS 439.890**)** "Sentinel event" has the meaning ascribed to it in NRS 439.830. (Added to NAC by Health Div. by R118-04, eff. 11-4-2004)

Sec. 6. NAC 439.915 Mandatory reports of sentinel events: Submission; form and contents. (NRS 439.835**,** 439.890**)**

1. A report submitted pursuant to NRS 439.835 must be submitted ~~[on]~~ ***in*** the ~~[form]~~ ***format*** prescribed pursuant to subsection 4 and must include~~[:]~~ ***, but not be limited to:***

    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 list of "serious reportable events" published by the National Quality Forum (NQF), adopted by reference and as amended and supplemented; and***

k. 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]~~ ***in*** the ~~[form]~~ ***format*** prescribed pursuant to subsection 4 and must include***, but not be limited to:***

(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) ***How each finding of the investigation of the sentinel event(s) will be addressed and corrected;***

(2) A review of the policies, procedures, or processes of the medical facility;

(3) Any change or development of the policies, procedures, or processes of the medical facility;

(4) Any disciplinary actions taken against a member of the staff of the medical facility by the medical facility;

(5) Any environmental or equipment changes made in the medical facility; ~~[and]~~

(6) Any education or retraining provided to the staff of the medical facility~~[.]~~ ***;***

(7) ***When each correction will be completed;***

(8) ***The responsible party for making the corrections;***

(9) ***What action will be taken to prevent each finding from reoccurring, including, without limitation:***

(a) Identification of changes/corrective actions that can be implemented to reduce risk, or formulation of a rationale for not implementing changes/corrective actions;

(b) The responsible party for implementation of the identified changes/corrective actions and when the changes will be implemented;

(c) Evaluation of the effectiveness of the corrective action plan and implementation of necessary changes to the plan based on the outcome of the plan's evaluation;

(d) Establishment of a monitoring schedule for assessing the effectiveness of the corrective action plan; and

(e) The responsible party for accomplishing and/or monitoring compliance with the corrective action plan. If the corrective action plan involves more than one person, the party who maintains ultimate responsibility; or

(f) If the medical facility determines there is no need to create a corrective action plan for the sentinel event, provide a written explanation of the reasons for not creating a corrective action plan to the Health Division.

10) Except as otherwise provided in NRS 239.0115, any information provided to the Health Division relating to the Corrective Action Plan, is confidential, not subject to subpoena or discovery and not subject to inspection by the general public.

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 format*** for each report required by subsection 1 or 2***, in a manner prescribed by the State Board of Health, as prescribed by subsection 3, Section 7 of Assembly Bill 206 of the 2009 legislative session. A copy of the investigation of the sentinel event(s) will be made available to the Health Division upon request. A copy of the corrective action plan required by subsection 2 must be submitted with the second report.*** The Division will distribute copies of the forms created pursuant to this subsection to each medical facility in this State. ***The Division will notify medical facilities of any updates to the forms within 30 days of making any changes.***

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. (Added to NAC by Health Div. by R118-04, eff. 11-4-2004)

6. If a facility suspects that a sentinel event may have occurred to a patient who was transferred or discharged from another facility, the receiving facility shall report the suspected sentinel event to the facility that initiated the transfer or discharge.

The facility in which the sentinel event occurred will report the sentinel event to the sentinel event registry.

Sec.7. *Investigation of a Sentinel Event(s)*

1. *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 medical facility at which the sentinel event occurred must conduct an investigation of the causes or contributing factors, or both of sentinel events. The investigation must determine whether system changes would likely prevent a sentinel event in similar circumstances. The investigation of a sentinel event(s) must follow the methodology and procedures related to a root cause analysis of one of the following organizations:*

   (a) The Joint Commission; or

   (b) The Department of Veterans Affairs National Center for Patient Safety; or

   (c) Another nationally recognized root cause analysis methodology.

2. *Except as otherwise provided in NRS 239.0115, any information provided to the Health Division relating to the investigation of a sentinel event(s) is confidential, not subject to subpoena or discovery and not subject to inspection by the general public.*

Sec. 8. *NHSN: Requirements to maintain enrollment in NHSN*

1. *Each medical facility that participates in NHSN shall comply with all NHSN requirements that are necessary to enroll and maintain enrollment in NHSN and adhere to the NHSN trainings set forth at the NHSN website: http://www.cdc.gov/nhsn/.*

2. *Each medical facility shall:*

   (a) Designate a NHSN Facility Administrator;

   (b) Designate NHSN Authorized Users for his or her medical facility if users are deemed necessary by the medical facility; and

   (c) Join the Health Division user group that allows the Health Division to access facility-acquired infection data that his or her medical facility submits to NHSN.

Sec 9. ***NHSN: Collection and Reporting of Data***

1. ***A medical facility that meets the criteria prescribed in subsection (1) of Section 4 of Senate Bill 319 of the 2009 legislative session shall routinely collect and submit the data required to be collected under Sub-section 3 to NHSN in accordance with NHSN definitions, methods, requirements, and procedures.***

2. ***A medical facility that meets the criteria prescribed in subsection (2) of Section 4 of Senate Bill 319 of the 2009 legislative session may routinely collect and submit data to NHSN. The data collected and submitted shall be collected in accordance with NHSN definitions, methods, requirements, and procedures.***

   (a) For hospitals, the requirement to report through NHSN will be determined by dividing the total number of acute inpatient days by 365.

   (b) For all other medical facilities, this will be determined by dividing the total number of patients seen each day by the total number of business days open that calendar year.

3. ***Each physician employed, credentialed and/or under contract with a medical facility, who performs a clinical procedure or surgery required by Sub-section 3, shall report to the medical facility at which the clinical procedure or surgery was performed a facility-acquired infection that the physician diagnoses at a follow-up appointment with the patient related to the clinical procedure or surgery.***

4. ***The Health Division will determine the categories of infections, procedures, and NHSN components that will be required to be reported through NHSN by medical facilities which meet the criteria in subsection (1) of Section 4 of Senate Bill 319 of the 2009 legislative session. These will be chosen in consultation with medical facilities, experts in infection control, and medical facility associations. The Health Division will maintain on its website the categories of infections, procedures, and NHSN components that will be required to be reported through NHSN.***

5. ***For facility-acquired infections for which the Health Division requires tracking and reporting as permitted by Sub-section 3, medical facilities shall be required to report a suspected or confirmed facility-acquired infection associated with another medical facility to the originating medical facility. Documentation of reporting should be maintained for a minimum of three years.***

Sec. 10. ***Confidentiality of Data***

1. ***Except as otherwise provided in NRS 239.0115, any information provided to the Health Division relating to facility-acquired infection data or procedures that the***

Health Division retrieves from NHSN is confidential, not subject to subpoena or discovery and not subject to inspection by the general public. The confidentiality of data provided to the Health Division in this section, does not preclude the Health Division from making available the public reports described in this section.

a. Annual public reports, using data collected from NHSN, will be posted on the Health Division's website. The Health Division will ensure that the information does not reveal the identity of a specific person. The report may include, but will not be limited to:

(1) The name of the specific medical facilities;

(2) An analysis of trends;

(3) The types of procedures and infections being reported on;

(4) Rates of infection; and/or

(5) Medical facility rate comparisons.

2. If figures generated from public health data pose the risk of compromising the identity of a patient or patients, the Health Division will adhere to standard methods of data suppression and reporting to assure patient confidentiality.

3. Medical facilities will be notified and given a review period of 10 calendar days when annual reports, using data collected from NHSN are posted on the Health Division's website, prior to becoming public, to review for accuracy.

Sec. 11. *Data Accuracy And Retention; Audits by the Health Division*

1. The chief executive officer, or his or her designee, of each medical facility shall submit in writing to the Health Division, by March 1st annually, a signed statement certifying that the facility has processes in place to ensure accurate submission of facility-acquired infection data in accordance with NHSN requirements during the current reporting year.

(a) The mailing address to which the chief executive officer, or his or her designee, shall submit the written certification is to: The Bureau of Health Care Quality and Compliance, 1550 College Parkway, Suite 158, Carson City, NV, 89706.

(b) The Health Division may conduct audits of each medical facility's facility-acquired infection data, health care records and tests on a routine or as needed basis.