ADOPTED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R044-10

Effective October 15, 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, 2012, 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 may prepare and post on the Internet website maintained by the Health Division a report of the data provided by a specific medical facility, including, without limitation, infections tracked by the medical facility, infection rates reported by the medical facility and the name of the medical facility, if:

(a) The medical facility has given the Health Division permission to make such a report available to the public; and

(b) The data released pursuant to this subsection does not reveal the identity or otherwise compromise the confidentiality of a medical facility that is included in the report of aggregated

data posted pursuant to subsection 2 and which has not given the Health Division permission to report data specific to that medical facility.

4. 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.

5. 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 in subsection 4, may be obtained free of charge from the National Quality Forum, 601 13th Street, N.W., 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 in subsection 4.

HEALTH DIVISION
Bureau of Healthcare Quality and Compliance
August 17, 2010
LCB File # R044-10
Information Statement per NRS 233B.066

1. A description of how public comment was solicited, a summary of public response, and an explanation how other interested persons may obtain a copy of the summary.
Public comment was solicited by the Notice of Public Hearing posted at Health Division locations, State Library and Archives, county libraries and mailed notification of the Notice of Public Hearing to affected stakeholders. In addition, two informal stakeholder meetings were held prior to workshop, and two workshops were also held, one in Las Vegas and one in Carson City. The following is a summary of the testimony provided during the State Board of Health Public Hearing on August 13, 2010:

All of those that testified were in support of the proposed regulations, none testified in opposition, although a few concerns were noted. One individual testified that one component of the proposed regulations should be implemented at a later date; two testified that they felt the proposed regulations should be strengthened to require additional reporting and transparency. A summary of the Hearing for Amendment of Nevada Administrative Code, Chapter 439 can be obtained by contacting the Bureau of Health Care Quality and Compliance, 1550 College Parkway, Suite 158, Carson City, NV 89706

2. The number of persons who:

(a) Attended the hearing;

(b) Testified at each hearing; and

(c) Submitted to the agency written statements.

One hundred forty individuals were present at the hearing. Leticia Metherell, Health Facilities Surveyor IV, Bureau of Health Care Quality and Compliance, presented the proposal to amend Nevada Administrative Code, Chapter 439. Seven individuals provided testimony. A summary of the testimony can be found in number one above.

3. A description of how comment was solicited from affected businesses, a summary of their response, and an explanation how other interested individuals may obtain a copy of the summary.

A Small Business Impact Questionnaire was sent to hospitals, ambulatory surgery centers, and independent centers of emergency medical care along with a copy of the proposed regulation changes, on January 21, 2010. Out of 155 small business impact questionnaires distributed, only two responses were received. The following is a summary of the two responses:

Summary of Response

Summary Of Comments Received (2 responses were received out of 155 small business impact questionnaires distributed)			
Will a specific regulation have an adverse economic effect upon your business?	**Will the regulation (s) have any beneficial effect upon your business?**	**Do you anticipate any indirect adverse effects upon your business?**	**Do you anticipate any indirect beneficial effects upon your business?**
Staff time needed for data collection and reporting requirements.	N/A	N/A	N/A
The paperwork involved is nothing more than a waste of trees.	N/A	I might decide to close my business due to more and more and more government regulations.	N/A

Number of Respondents out 155	**Adverse economic effect?**	**Beneficial effect?**	**Indirect adverse effects?**	**Indirect beneficial effects?**
1	YES	NO	POSSIBLE	NO
2	YES	NO	YES	NO

A summary of the Hearing for Amendment of Nevada Administrative Code, Chapter 439 can be obtained by contacting the Bureau of Health Care Quality and Compliance, 1550 College Parkway, Suite 158, Carson City, NV 89706.

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. The statement should also explain the reasons for making any changes to the regulation as proposed.

There were two (2) changes made to the proposed regulations. The first change, noted below in ***bold, underlined italics***, changes the starting date for reporting surgical site infections from June 1, 2011 to June 1, 2012. This was since at the request of the Nevada Hospital Association, to allow for a gradual transition into the reporting requirements. This would allow facilities time to learn the new reporting system and not be overwhelmed with data allowing for increased quality of the information submitted.

1. (e) Commencing not later than ~~June 1, 2011~~ ***June 1, 2012,*** submit data to the National Healthcare Safety Network concerning surgical site infections related to a:

The second change, noted below in ***bold, underlined italics,*** would add a subsection to Section 10 of the proposed regulations to allow facilities to report facility specific data with their permission as long as it does not compromise the identity of other facilities in the aggregated report, since the proposed regulations only allowed for aggregated reporting of the National Healthcare Safety (NHSN) data. The original intent was to have facility specific data reported and that was how the proposed regulations went to LCB. LCB interpreted federal law as prohibiting reporting on facility specific data. The Health Division then made the decision to remove the reporting of facility specific data from the proposed regulations based on this interpretation. The proposed regulations came back to the Health Division only reflecting the reporting of aggregated data. Stakeholder input revealed that the desire to report facility specific data continued to exist. LCB stated that facility specific data could be reported with the permission of the facility as long as it did not compromise the aggregated data and still be in compliance with federal law, therefore, the change in the proposed regulations.

Section 10 (top of page 9): A new subsection 3 is being added.

3. In addition to the report required by subsection 2, the Health Division may report data provided by specific medical facilities, including, without limitation, infections tracked by a specific medical facility, infection rates reported by a specific medical facility and the names of those medical facilities, if:

a) The medical facility has provided permission for such reports; and
b) Reporting the information for medical facilities which have given permission does not compromise the identity of other facilities whose information was included in the aggregated report pursuant to subsection 2.

These proposed regulations along with the errata were approved by the State Board of Health on August 13, 2010.

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

- Beneficial effects:
  There is no imposition of new fees. There is no cost to join the National Healthcare Safety Network (NHSN). Reporting through NHSN is voluntary for medical facilities which have an average of less than 25 patients during each business day in the immediately preceding calendar year. As a result many small businesses are excluded from this reporting requirement. Increased awareness of healthcare associated infections (HAIs) may lead to a reduction in HAIs with a potential cost savings of thousands to millions of dollars, as well as a reduction in patient suffering and death.
- Adverse effects:
  There may be some increased surveillance and data entry time of HAIs in units that hospitals may not have monitored in the past, due to the requirement for organizational wide surveillance. This may result in an increase in work load to accomplish this.
- There is no estimated economic effect to be imposed on the public due to the proposed regulations.

b. Both immediate and long term effects.

- Immediate effects: May lead to increase data entry and surveillance of certain HAIs, resulting in an increase in workload.
- Long term effects: A reduction in HAI's may result in a potential for significant costs savings which may off-setting the increased costs needed for additional surveillance.
- The effects to the public may be reduced HAIs, leading to a decrease in patient suffering and death.

6. The estimated cost to the agency for enforcement of the proposed regulation.

Estimated cost to the agency for enforcement of the proposed regulations is minimal.

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 regulatory federal agency.

There is no known overlap or duplication of the proposed regulations with other state, federal, or other government agencies regulations.

8. The regulation includes provisions which are more stringent than a federal regulation which regulates the same activity, a summary of such provisions.

Not applicable as there are no known federal regulations that require the same activity.

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.

No new fees or increases in existing fees will occur as a result of these proposed regulations.

10. If the proposed regulation is likely to impose a direct and significant economic burden upon a small business or directly restrict the formulation, operation or expansion of a small business. What methods did the agency use in determining the impact of the regulation on a small business?

It is not anticipated that these proposed regulations would impose a direct and significant economic burden upon a small business.

SMALL BUSINESS IMPACT STATEMENT 2010

PROPOSED AMENDMENTS TO NAC 439

The Bureau of Health Care Quality and Compliance (BHCQC) has determined that the proposed amendments should not impose a significant economic burden upon a small business or directly restrict the formation, operation or expansion of a small business in Nevada.

A small business is 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 of their response and an explanation of the manner in which other interested persons may obtain a copy of the summary.

Background

Sentinel Event Reporting

The proposed changes will revise Chapter 439 of the Nevada Administrative Code. These regulation changes are being proposed in accordance with Senate Bill 319, of the 2009 legislative session. The proposed regulations provide guidelines for determining whether a sentinel event has occurred, and requirements for reporting of sentinel events, root cause analyses, corrective action plans, and completion of specific forms.

National Healthcare Safety Network (NHSN) Reporting

The proposed regulations include National Healthcare Safety Network (NHSN) reporting requirements. NHSN is a secure, internet-based surveillance system established by the Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services that will be used to conduct surveillance of infection control issues. The proposed regulations address the following items regarding NHSN reporting:

a. Enrollment and Training Requirements;
b. Confidentiality of Data, including what may be publicly reported;
c. Collection and Reporting of Data; and
d. Data Accuracy and Retention

Pursuant to NRS 233B.0608(2)(a), the Bureau of Healthcare Quality and Compliance has requested input from hospitals, ambulatory surgery centers, and independent centers of emergency medical care.

A Small Business Impact Questionnaire was sent to hospitals, ambulatory surgery centers, and independent centers of emergency medical care along with a copy of the proposed regulation changes, on January 21, 2010. The questions on the questionnaire were:

1) How many employees are currently employed by your business?
2) Will a specific regulation have an adverse economic effect upon your business?
3) Will the regulation(s) have any beneficial effect upon your business?
4) Do you anticipate any indirect adverse effects upon your business?
5) Do you anticipate any indirect beneficial effects upon your business?

Summary of Response

Summary Of Comments Received (2 responses were received out of 155 small business impact questionnaires distributed)			
Will a specific regulation have an adverse economic effect upon your business?	**Will the regulation (s) have any beneficial effect upon your business?**	**Do you anticipate any indirect adverse effects upon your business?**	**Do you anticipate any indirect beneficial effects upon your business?**
Staff time needed for data collection and reporting requirements.	N/A	N/A	N/A
The paperwork involved is nothing more than a waste of trees.	N/A	I might decide to close my business due to more and more and more government regulations.	N/A

Number of Respondents out 155	**Adverse economic effect?**	**Beneficial effect?**	**Indirect adverse effects?**	**Indirect beneficial effects?**
1	YES	NO	POSSIBLE	NO
2	YES	NO	YES	NO

Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to Stephanie Robbins at the Bureau of Healthcare Quality and Compliance at:

Bureau of Healthcare Quality and Compliance
1550 College Parkway, Suite 158
Carson City, NV 89706

Stephanie Robbins, Administrative Assistant III
Phone: 775-687-4475, Extension 251
Email: srobbins@health.nv.gov

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 and both direct and indirect effects.

a. There is no imposition of new fees.

b. There is no cost to join the National Healthcare Safety Network (NHSN)

c. Reporting through NHSN is voluntary for medical facilities which have an average of less than 25 patients during each business day in the immediately preceding calendar year. As a result many small businesses are excluded from this reporting requirement.

d. There may be some increased data entry time.

e. In conjunction with health informatics software companies, the Centers for Disease Control and Prevention has adopted the clinical document architecture (CDA) format to allow data already entered in a health facility's data management system to be exported according to the XML standard and subsequently uploaded into the National Healthcare Safety Network (NHSN). This would eliminate the burden of duplicate data entry by facilities utilizing this software.

3) A description of the methods that BHCQC considered to reduce the impact of the proposed regulation on small businesses and statement regarding whether the agency actually used those methods.

The Bureau of Healthcare Quality and Compliance has held several opportunities for medical facilities to provide input and comments regarding the proposed SB 319 regulations, including the economic impact the proposed regulations may have on medical facilities. Modifications to the proposed regulations have been made as a result of this input. Workshops will be held on March 3 and 4, 2010 allowing for further input by medical facilities regarding the proposed regulations and how they will impact medical facilities. These comments will be taken into consideration for possible further revisions to the regulations to reduce the economic impact on facilities.

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

Estimated cost to the agency for enforcement of the proposed regulations is minimal.

5) Total amount BHCQC expects to collect from any fees and the manner in which the money will be used

No anticipated increase.

6) An explanation of why any duplicative or more stringent provisions than federal, state or local standards regulating the same activity are necessary.

The requirement for certain medical facilities to participate in the National Healthcare Safety Network (NHSN) is a new requirement imposed by Senate Bill 319 of the 2009 legislative session. Senate Bill 319 also requires a medical facility which reports a sentinel event to conduct an investigation into the cause of the event and to implement a plan to remedy the cause. The proposed regulations address these issues.