

Governor Jim Gibbons



For Immediate Release: March 10, 2008

GOVERNOR TO ADDRESS STATEWIDE HEALTH CONCERNS

Carson City— Governor Jim Gibbons has scheduled a news conference at 1:00PM on Monday March 10, 2008. The purpose of this news conference is to provide updates on the health care problems recently encountered at several facilities around the state.

WHO: Nevada Governor Jim Gibbons
Nevada State Senator Randolph Townsend-Chairman of the Legislative Commission, Chairman of Senate Committee on Commerce and Labor
Nevada State Senator Bob Beers: Vice-Chair, Interim Finance Committee
Mike Willden-Director of the Nevada Department of Health and Human Services
Dr. Rudy Manthei-President of the Nevada Ambulatory Surgery Centers Association.

WHAT: News Conference
WHEN: 1:00PM Monday March 10, 2008
WHERE: Governor's Office, Capitol Building, Carson City, Nevada
WHY: Update and discuss current health crisis

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OUTPATIENT SURGERY CENTERS INVESTIGATION
AND FOCUSED SAFETY REVIEWS

BACKGROUND/HISTORY

- In early January 2008 the Southern Nevada Health District (SNHD) received reports of three (3) acute cases of Hepatitis C. Additional investigative work identified three (3) additional cases, for a total of six (6) cases. Five of the cases had procedures requiring anesthesia on the same date (September 2007) at the Endoscopy Center of Nevada.
- Following a joint investigation with the Nevada State Bureau of Licensure and Certification (BLC) and the Centers for Disease Control and Prevention (CDC), the Health District determined that unsafe injection practices exposed patients to the blood of other patients.
- Approximately 40,000 patients of the Endoscopy Center of Nevada were sent letters during the last week of February 2008, by SNHD, advising them of the identified use of unsafe practices and recommended the patients be tested for Hepatitis C, Hepatitis B and HIV.
- Several surgery centers (with related ownership) were closed by local government orders to protect public health.
- No additional cases of positive Hepatitis C testing have been confirmed.

HELPLINE & PATIENT RESOURCES FOR TESTING

- SNHD established a helpline and website to assist patients with information and to identify testing resources.
 - Helpline (702) 759-INFO
(702) 759-4636
 - Website www.southernnevadahealthdistrict.org
- Most patients affected have insurance and can get testing done through their insurance program. Co-pays have been waived by most carriers. (Insurance Commissioner approval given.)

- Testing labs have offered discounted/free testing
- UMC QuickCares and Nevada Community Health Centers are also providing discounted services.
- \$50,000 donated by Anthem Blue Cross to assist with screening/testing costs.
- Bottom line is ---no one should go without testing because of financial concerns.

STATE HEALTH ACTIONS

- Based on concerns seen in Las Vegas ASC's in early investigation process a decision was made to review all fifty (50) licensed ASC's. Focused surveys were started statewide.
- To date (3-7-08) 23 of 50 ASC's have been reviewed by BLC, with plans to review the remaining ASC's within 5-7 working days.
 - 14 ASC's reviewed in Northern Nevada
 - 9 ASC's reviewed in Southern Nevada
- Reviewed findings are being posted on the Health Division website at <http://health.nv.gov>, along with specific Statement of Deficiencies and Plans of Correction submitted by the ASC's.
- Governor Gibbons approved emergency regulations on March 6, 2008 requiring ASC's to 1) maintain an infection control program in accordance with acceptable standards of practice, and 2) provide drugs (medicine) in a safe and effective manner in accordance with accepted standards and following manufacturing instructions.
- Requested assistance from the CDC to help with the ongoing review of the ASC's. CDC is providing Infection Control Specialists on-site beginning the week of March 10, 2008, as needed.

HEALTH DIVISION

Bureau of Licensure and Certification

LCB File No. Emergency Regulations

March 6, 2008

Surgical Center for Ambulatory Patients

Information Statement per NRS 233B.066

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.

No public comment was solicited as these are emergency regulation amendments.

2. THE NUMBER OF PERSONS WHO:

(A) ATTENDED THE HEARING;

There was no hearing.

(B) TESTIFIED AT EACH HEARING; AND

There was no hearing.

(C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

None.

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

No small business impact summary was submitted.

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 Governor's Office has endorsed the following proposed regulation amendments:

NAC 449.9812 Program for quality assurance. (NRS 449.037)

5. The facility shall establish and maintain an infection control program designed in accordance with acceptable standards of practice to prevent the development and transmission of disease and infection.

5- 6. Activities conducted pursuant to the program for quality assurance must be reported to the appropriate members of the staff and to the governing body. The administrator of the center shall establish procedures for carrying out any recommendations of the governing body.

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6-7. As used in this section, "health care practitioner" means a person who is licensed or certified to provide health care services in this State, including, without limitation, a physician, dentist, podiatrist, and registered or licensed practical nurse.

NAC 449.990 Medication and treatment. (NRS 449.037)

4. *The facility shall provide drugs and biologicals in a safe and effective manner in accordance with accepted professional practice and following manufacturer's instructions.*

5. *Drugs must be prepared and administered according to established policies, acceptable standards of practice and manufacturers instructions.*

—4. 6. Records must be maintained for any substance listed as a schedule-II controlled substance pursuant to chapter 453 of NRS. Any such record must indicate the name of the patient, the name of the prescriber, the name of the controlled substance, the strength and dose administered, and the balance of the controlled substance remaining. A count must be made of all such controlled substances at the change of each nursing shift by a nurse from each shift. The count must be authenticated by both nurses.

5. 7. Transfusions of blood or intravenous medications may be administered only by persons who have been specially trained and are authorized for that duty. An ambulatory surgical center shall adopt policies and procedures for the administration of blood.

6. 8. Any suspected adverse reaction to a transfusion or medication must be reported by members of the nursing staff to the physician attending the patient. The nursing staff shall note the reaction in the medical record of the patient. Any suspected reaction to a transfusion must also be reported to the service that furnished the blood.

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

There are no adverse effects on Surgical Centers for Ambulatory Patients. There are no adverse effects on the public.

These additional regulations will provide specific requirements to ambulatory surgery centers to follow to ensure the safe delivery of medications and to establish effective programs for infection control.

(B) BOTH IMMEDIATE AND LONG TERM EFFECTS.

The immediate effects would be for Surgical Center for Ambulatory Patients to implement systems for establishing and maintaining medications in a safe manner to patients. The immediate effects on the public will be to protect patient safety.

Same as above for long term effects on the business and public.

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

There is no anticipated additional cost to the agency for 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.

There is no duplication or overlap of other state or local government agency's 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.

These proposed regulations do not overlap or duplicate federal regulations. The regulations do have a counterpart in the code of federal regulations. The additional requirements are:

- 4. The facility shall provide drugs and biologicals in a safe and effective manner in accordance with accepted professional practice and following manufacturer's instructions.*
- 5. Drugs must be prepared and administered according to established policies, acceptable standards of practice and manufacturers instructions.*

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.

These amendments do not establish new fees.

10. IS THE PROPOSED REGULATION 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? WHAT METHODS DID THE AGENCY USE IN DETERMINING THE IMPACT OF THE REGULATION ON A SMALL BUSINESS?

These regulations impose no economic burden.

- The Health Division can be reached by calling (775) 684-5900 or toll free 1-800-992-0900 (ask for ext. 5900)

FISCAL/STAFFING

- BLC includes 60 staff in total, with 50 of the staff being Health Facilities Surveyors.
- Presently 17.51 (14 surveyors) positions are vacant. Historically health surveyors are difficult to recruit and retain.
- No cuts were made to the BLC budget in the 4.5% spending reductions plans.
- ASC's pay the following fees (FY06=\$112,034, FY07 \$121,175)
 - Initial \$3,570
 - Renewal \$1,785 yearly
- FY2007 BLC expenditures totaled \$6.2 million. A little more than half was funded by "fees" and the remainder "federal" funds.
- The BLC budget has a significant cash reserve. \$5.2 million was carried forward from FY07 to FY08.
- The Health Facilities Administrative Penalty account (BA3217) also is available if needed, totaling \$233,588.
- Governor Gibbons has instructed DHHS to use necessary funding to complete all ASC surveys as quickly as possible. The Governor has also authorized DHHS to request use of the Disaster Relief Fund if necessary.
- The issue of "fee increases" during the 2007 Legislature us not why BLC is currently short of resources (manpower). Difficulty in recruiting/retaining qualified staff is the primary reason.

JIM GIBBONS
Governor

MICHAEL J. WILLEN
Director



RICHARD WHITLEY, M.S.
Administrator

State Health Officer

STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH DIVISION
BUREAU OF LICENSURE AND CERTIFICATION

Health Facilities/Lab Services
1550 College Parkway
Suite 158
Carson City, Nevada 89706
(775) 687-4475
Fax: (775) 687-4888

Health Facilities/Lab Services
4220 S. Maryland Parkway
Suite B10 Building D
Las Vegas, Nevada 89119
(702) 486-8516
Fax: (702) 486-6620

Emergency Medical Services
4150 Technology Way
Suite 200
Carson City, Nevada 89706
(775) 887-7593
Fax: (775) 887-7595

Emergency Medical Services
1000 Ruby Vista Drive
Suite 103
Elko, Nevada 89801
(775) 753-1154
Fax: (775) 753-4112

Emergency Medical Services
P.O. Box 1079
Tonopah, Nevada 89049
(775) 462-5322
Fax: (775) 462-6975

March 7, 2008

Dear Administrator:

Nevada Administrative Code Chapter 449 Regulations for a Surgical Center for Ambulatory Patients has been amended, effective March 6, 2008. The additional language added to the regulations provides more specific wording for licensed surgical centers to make clear their requirement to ensure the safe delivery of medications and to establish effective programs for infection control.

Please be aware the effective date of the amendments was March 6, 2008 and your facility must be able to demonstrate compliance with these regulations immediately.

The description of the emergency situation requiring these additional requirements, the amendments to the regulations, and an information statement is included for your review. The Bureau of Licensure and Certification website will be updated to include this information and may be accessed at www.health.nv.gov.

If you have any questions regarding the amended regulations please contact our office at 775-687-4475.

Sincerely,

Jennifer Dunaway, HFS IV
For Lisa Jones, Chief

Encl. As Stated

SECRETARY OF STATE
 FILING DATA
 MISS MILLER
 SECRETARY OF STATE
Stokes
 2008 MAR -6 PM 1:53
 CLERK OF COURTS
 NEVADA

For Filing Administrative Regulations

(LCB File No.)

Agency...State Board of Health.

FOR EMERGENCY REGULATIONS ONLY
 Effective date... *March 6, 2008*
 Expiration date... *July 4, 2008*
Jim Gibbons
 Governor's Signature

Classification: PROPOSED ADOPTED BY AGENCY EMERGENCY

Brief description of action.....

The Bureau of Licensure and Certification within the Health Division is requesting approval to amend regulations for Chapter 449 Surgical Center for Ambulatory Patients (ASC) in response to deficiencies identified in the administration of anesthesia medication during a diagnostic or surgical procedure, and the unsafe injection practices causing a significant detriment to the public health and safety. A total of six cases of Hepatitis C have been identified, five of the cases had procedures requiring injected anesthesia on the same day. Endoscopy Center of Southern Nevada was identified by the Bureau of Licensure and Certification staff as administering single dose medications to multiple patients, an unsafe practice. The Southern Nevada Health District also identified the re-use of syringes. Desert Shadow Endoscopy Center was also administering single dose vials of anesthesia medication on multiple patients. At the Gastrointestinal Diagnostic Center, a separately owned facility, an immediate jeopardy situation was identified as a result of an anesthesiologist reusing syringes to administer medications to multiple patients and the use of single dose medication vials for multiple patients. These were all potential sources of contamination between patients. These additional regulations will provide specific requirements to surgical centers for ambulatory patients to follow to ensure the safe delivery of medications and to establish effective programs for infection control.

Authority citation other than 233B: NRS 449.037

Notice date: _____

Date of Adoption by the Agency:

Hearing date: _____

March 6, 2008

Health Division Emergency Regulation
Nevada Administrative Code Chapter 449

The Bureau of Licensure and Certification within the Health Division is requesting approval to amend regulations for Chapter 449 Surgical Center for Ambulatory Patients (ASC) in response to deficiencies identified in the administration of anesthesia medication during a diagnostic or surgical procedure, and the unsafe injection practices causing a significant detriment to the public health and safety.

Endoscopy Center of Southern Nevada was identified by the Bureau of Licensure and Certification staff as administering single dose medications to multiple patients, an unsafe practice. The Southern Nevada Health District also identified the re-use of syringes. A total of six cases of Hepatitis C have been identified, five of the cases had procedures requiring injected anesthesia on the same day.

Desert Shadow Endoscopy Center was also administering single dose vials of anesthesia medication on multiple patients.

At the Gastrointestinal Diagnostic Center, a separately owned facility, an immediate jeopardy situation was identified as a result of an anesthesiologist reusing syringes to administer medications to multiple patients and the use of single dose medication vials for multiple patients. These were all potential sources of contamination between patients.

These additional regulations will provide specific requirements to surgical centers for ambulatory patients to follow to ensure the safe delivery of medications and to establish effective programs for infection control.

Proposed Regulation Amendments:

Nevada Administrative Codes (NAC) 449.9812

NAC 449.9812 Program for quality assurance. (NRS 449.037)

1. The administrator of an ambulatory surgical center shall establish a program for quality assurance for the center.
2. The program for quality assurance must include, without limitation:
 - (a) Periodic reviews of the clinical responsibilities and authority of the members of the staff.
 - (b) Periodic evaluations of members of the staff that are conducted by their peers.
 - (c) Procedures for the supervision of the professional and technical activities of the members of the staff.
 - (d) Periodic evaluations that are conducted to determine whether the clinical and administrative policies of the center are cost-effective. The evaluations required by this paragraph must not be limited to the cost-effectiveness of the administrative policies of the center.
 - (e) Procedures for identifying and correcting any problems or concerns that provide an opportunity for all members of the staff who are health care practitioners to participate in the program for quality assurance.

(f) Techniques for self-assessment that are required to be used by the members of the staff and provide for an examination of the manner in which care has been, is and will be provided and the quality of the care provided.

(g) Procedures for identifying and addressing any problems or concerns related to the care provided to patients using the medical records of the center and any other sources of data that may be useful to identify previously unrecognized concerns, and for assessing the frequency, severity and sources of suspected problems and concerns. The procedures must include, without limitation, procedures for assessing:

- (1) The clinical performances of members of the staff who are health care practitioners;
 - (2) The standards used for the maintenance of medical records;
 - (3) The procedures used to control the quality of radiological, pathological, laboratory and pharmaceutical services provided by the center;
 - (4) The procedures used to control the quality of other professional and technical services provided by the center;
 - (5) The care and services provided by the extended recovery unit, if such a unit is operated by the center;
 - (6) The procedures used to control infection; and
 - (7) The satisfaction of patients who have been treated at the center.
- (h) The maintenance of a record of all fires and deaths that have occurred at the center and the transfer of all patients from the center to a hospital.
- (i) Procedures for assessing any actions taken to correct identified problems or concerns and for determining whether the actions taken have achieved or sustained the desired result and, if not, why not.

3. The members of the professional and administrative staffs of the center shall:

- (a) Understand, support and participate in the program for quality assurance; and
- (b) Participate in the resolution of any problems and concerns identified pursuant to the procedures required by subsection 2.

4. The members of the staff who are health care practitioners shall participate in the development and application of the criteria used to evaluate the care provided at the center and the evaluation of any problems and concerns identified pursuant to the procedures required by subsection 2.

5. *The facility shall establish and maintain an infection control program designed in accordance with acceptable standards of practice to prevent the development and transmission of disease and infection.*

5-6. Activities conducted pursuant to the program for quality assurance must be reported to the appropriate members of the staff and to the governing body. The administrator of the center shall establish procedures for carrying out any recommendations of the governing body.

6-7. As used in this section, "health care practitioner" means a person who is licensed or certified to provide health care services in this State, including, without limitation, a physician, dentist, podiatrist, and registered or licensed practical nurse.
(Added to NAC by Bd. of Health by R049-99, eff. 9-27-99)

NAC 449.990 Medication and treatment. (NRS 449.037)

1. Any medication or treatment may be given only upon the written or oral order of a person lawfully authorized to prescribe that medication or treatment. This order must be

authenticated by the prescriber and the person administering the medication. An oral order must be recorded and authenticated within 24 hours after it is made.

2. Medications prepared by one nurse may not be administered by another nurse.
3. At the time the medication is administered, the patient must be identified and the medication must be identified as being ordered for that patient and recorded in the medical record of the patient.
4. *The facility shall provide drugs and biologicals in a safe and effective manner in accordance with accepted professional practice and following manufacturer's instructions.*
5. *Drugs must be prepared and administered according to established policies, acceptable standards of practice and manufacturers instructions.*

4. 6. Records must be maintained for any substance listed as a schedule II controlled substance pursuant to chapter 453 of NRS. Any such record must indicate the name of the patient, the name of the prescriber, the name of the controlled substance, the strength and dose administered, and the balance of the controlled substance remaining. A count must be made of all such controlled substances at the change of each nursing shift by a nurse from each shift. The count must be authenticated by both nurses.

~~5. 7. Transfusions of blood or intravenous medications may be administered only by persons who have been specially trained and are authorized for that duty. An ambulatory surgical center shall adopt policies and procedures for the administration of blood.~~

6. 8. Any suspected adverse reaction to a transfusion or medication must be reported by members of the nursing staff to the physician attending the patient. The nursing staff shall note the reaction in the medical record of the patient. Any suspected reaction to a transfusion must also be reported to the service that furnished the blood.

(Added to NAC by Bd. of Health, eff. 12-1 5-88; A by R049-99,9-27-99)

Endorsed this date March 6, 2008 by


Honorable Jim Gibbons, Governor of the State of Nevada



STATE OF NEVADA
Department of Health and Human Services
State Health Division

- Patient Safety Information
- Focus Surveys of all Ambulatory Surgery Centers (ASCs)
- ASC Statements of Deficiencies/Plans of Correction
- Emergency Regulations

State Phone Line

State Health Division Website

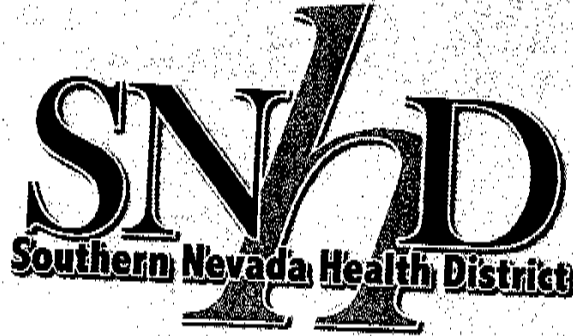
(775) 684-5900
24/7 Service

<http://health.nv.gov>

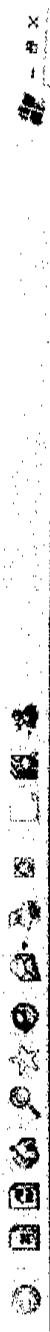
--or--

~~1-800-992-0900~~
ext. 45900
Monday-Friday
8:00 AM to 5:00 PM

- Patient Safety
- Ambulatory Surgical Center Actions
- ASC Focused Survey Status



- Hepatitis C Investigation
- Patient Resources
- Frequently Asked Questions (FAQs)
- SNHD Help Line
(702) 759-INFO (4636)
- SNHS Website
www.southernnevadahealthdistrict.org



Nevada Department of Health and Human Services
Nevada State Health Division

Welcome to the Nevada State Health Division

Nevada State Health Division promotes and protects the health of all Nevadans and restores to the state through its leadership in public health and enforcement of laws and regulations pertaining to public health. In fulfilling its mission, the Nevada State Health Division is guided by the State Board of Health and administers six bureaus.

Office of Autism Services

2007 Overview of Health Division Programs

What's New

- ★ SHAD Hepatitis C Investigation
- ★ Patient Safety Epidemiology Newsletter

Consumer Information

- ★ Adult Day Care Complaint Information
- ★ Request Complaint Information
- ★ Ambulatory Surgical Center Actions
- ★ ASC Focused Survey Status
- ★ Nevada Clean Air Indoor Act (Complaint)

Health Topics

- ★ 2008 HHS Poverty Guidelines
- ★ Autism Services
- ★ Health Division Budget Presentation
- ★ J-1/Conrad 30
- ★ Leukemia Clusters
- ★ Pandemic Flu
- ★ West Nile Virus
- ★ What Nevadans Need to Know About Influenza
- ★ Whooping Cough (Pertussis)

Quick Reference for Bureau Programs

- Bureau of Community Health**
ADAP - Asthma - Cancer - Diabetes - Hepatitis - HIV/AIDS - Immunizations - Injury - Obesity - Oral Health Care - Tobacco - Women's Health - Conception
- Bureau of Early Intervention Services**
Early Childhood - IDEA - Emergency Coordinating Council
- Bureau of Family Health Services**
Child's Assessment - Health - CHCN - Injury Prevention - Neonatal Child Health - Oral Health - STI - WIC
- Bureau of Health Planning & Statistics**
Center for Health Quality Research - Central Cancer Registry - Priority Care - Surgical Facility - Vital Statistics - WIC/SAFE
- Bureau of Health Protection Services**
Environmental Health - Radiological Health
- Bureau of Licensure & Certification**
Clinical Laboratory - Diagnostic - EMS - Health Facilities - Medical Facilities - Medical Laboratory Services
- Public Health Preparedness**
Epidemiology & Surveillance - Health Alert Network - West Nile Virus

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- Office of Minority Health
- Public Information Office
- State Health Officer
- State of Nevada
- Trust Fund for Public Health

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Translate