ADOPTED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R179-09

Effective July 22, 2010

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

AUTHORITY: §§1 and 16-34, NRS 441A.120 and 449.448; §§2-8 and 14, NRS 449.448; §9, NRS 449.442, 449.443 and 449.448; §10, NRS 449.443, 449.446 and 449.448; §11, NRS 449.442, 449.444 and 449.448; §12, NRS 449.444 and 449.448; §13, NRS 449.442 and 449.448; §§15 and 35-74, NRS 449.447 and 449.448; §§75 and 76, NRS 449.037.

A REGULATION relating to public health; establishing provisions for the permitting of certain offices of physicians and other facilities which provide health care; prescribing a fee for the issuance and renewal of a permit; prescribing the national accreditation required of those offices and facilities; requiring certain offices of physicians and related facilities to establish a program for the prevention and control of infections and communicable diseases; prescribing sanctions; and providing other matters properly relating thereto.

Section 1. NAC 441A.375 is hereby amended to read as follows:

441A.375 1. A case having tuberculosis or suspected case considered to have tuberculosis in a medical facility ***,*** **[**~~or~~**]** a facility for the dependent ***or outpatient facility*** must be managed in accordance with the guidelines of the Centers for Disease Control and Prevention as adopted by reference in paragraph (h) of subsection 1 of NAC 441A.200.

2. A medical facility, a facility for the dependent ***,*** **[**~~or~~**]** a home for individual residential care ***or an outpatient facility*** shall maintain surveillance of employees of the facility or home for tuberculosis and tuberculosis infection. The surveillance of employees must be conducted in accordance with the recommendations of the Centers for Disease Control and Prevention for preventing the transmission of tuberculosis in facilities providing health care set forth in the

guidelines of the Centers for Disease Control and Prevention as adopted by reference in paragraph (h) of subsection 1 of NAC 441A.200.

3. Before initial employment, a person employed in a medical facility, a facility for the dependent ***,*** ~~[or]~~ a home for individual residential care ***or an outpatient facility*** shall have a:

(a) Physical examination or certification from a licensed physician that the person is in a state of good health, is free from active tuberculosis and any other communicable disease in a contagious stage; and

(b) Tuberculosis screening test within the preceding 12 months, including persons with a history of bacillus Calmette-Guerin (BCG) vaccination.

➥ If the employee has only completed the first step of a 2-step Mantoux tuberculin skin test within the preceding 12 months, then the second step of the 2-step Mantoux tuberculin skin test or other single-step tuberculosis screening test must be administered. A single annual tuberculosis screening test must be administered thereafter, unless the medical director of the facility or his designee or another licensed physician determines that the risk of exposure is appropriate for a lesser frequency of testing and documents that determination. The risk of exposure and corresponding frequency of examination must be determined by following the guidelines of the Centers for Disease Control and Prevention as adopted by reference in paragraph (h) of subsection 1 of NAC 441A.200.

4. An employee with a documented history of a positive tuberculosis screening test is exempt from screening with skin tests or chest radiographs unless he develops symptoms suggestive of tuberculosis.

5. A person who demonstrates a positive tuberculosis screening test administered pursuant to subsection 3 shall submit to a chest radiograph and medical evaluation for active tuberculosis.

6. Counseling and preventive treatment must be offered to a person with a positive tuberculosis screening test in accordance with the guidelines of the Centers for Disease Control and Prevention as adopted by reference in paragraph (g) of subsection 1 of NAC 441A.200.

7. A medical facility shall maintain surveillance of employees for the development of pulmonary symptoms. A person with a history of tuberculosis or a positive tuberculosis screening test shall report promptly to the infection control specialist, if any, or to the director or other person in charge of the medical facility if the medical facility has not designated an infection control specialist, when any pulmonary symptoms develop. If symptoms of tuberculosis are present, the employee shall be evaluated for tuberculosis.

8. As used in this section, "outpatient facility" has the meaning ascribed to it in section 7 of this regulation.

Sec. 2. Chapter 449 of NAC is hereby amended by adding thereto the provisions set forth as sections 3 to 74, inclusive, of this regulation.

Sec. 3. ***As used in sections 3 to 74, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 4 to 8, inclusive, of this regulation have the meanings ascribed to them in those sections.***

Sec. 4. ***"Bureau" means the Bureau of Health Care Quality and Compliance of the Health Division.***

Sec. 5. ***"Health Division" means the Health Division of the Department of Health and Human Services.***

Sec. 6. ***"Inspection" means the inspection of an outpatient facility conducted by employees of the Bureau pursuant to NRS 449.443 or 449.446. The term includes a follow-up***

inspection to renew the permit of an outpatient facility or evaluate compliance with a plan of correction or an inspection made in response to a complaint.

Sec. 7. *"Outpatient facility" means an office of a physician or a facility that provides health care, other than a medical facility, which offers to a patient a service of general anesthesia, conscious sedation or deep sedation. The term does not include an office of a physician or a facility to which the provisions of NRS 449.435 to 449.448, inclusive, do not apply.*

Sec. 8. *"Treatment" means any medication, drug, test or procedure conducted or administered to diagnose or remedy a physical or mental illness or condition.*

Sec. 9. *1. Before offering to a patient a service of general anesthesia, conscious sedation or deep sedation, an outpatient facility shall submit to the Health Division an application for a permit to offer those services at the outpatient facility on a form prescribed by the Health Division.*

2. An application for a permit must:

(a) Be complete and notarized.

(b) Be accompanied by the appropriate application fee as prescribed in subsection 3.

(c) Include:

(1) The name of the applicant and, if a natural person, evidence that the applicant has attained the age of 21 years.

(2) The location of the outpatient facility.

(3) In specific terms, the nature of services and type of care to be offered.

(4) The name of the person in charge of the facility.

(5) Such other information as may be required by the Health Division for the proper administration and enforcement of NRS 449.435 to 449.448, inclusive, and sections 3 to 74, inclusive, of this regulation.

(6) Evidence satisfactory to the Health Division that the applicant is of reputable and responsible character. If the applicant is a firm, association, organization, partnership, business trust, corporation or company, similar evidence must be submitted as to the members thereof, and the person in charge of the outpatient facility for which application is made. If the applicant is a political subdivision of the State or other governmental agency, similar evidence must be submitted as to the person in charge of the outpatient facility for which application is made.

(7) Evidence satisfactory to the Health Division of the ability of the applicant to comply with the standards and regulations adopted by the Board.

(8) Evidence satisfactory to the Health Division that the facility:

(I) Conforms to the zoning regulations of the local government within which the outpatient facility will be operated; or

(II) Has applied for an appropriate reclassification, variance, permit for special use or other exception for the outpatient facility.

(d) Be accompanied by:

(1) Except as otherwise provided in subparagraph (2), proof of accreditation by a nationally recognized organization approved by the Board pursuant to section 13 of this regulation; or

(2) If the application is for an initial permit, evidence that the outpatient facility has applied for accreditation by a nationally recognized organization approved by the Board pursuant to section 13 of this regulation.

3. An applicant for a permit must pay to the Health Division a nonrefundable fee of $3,570.

4. An application for a permit is valid for 1 year after the date on which the application is submitted. If an applicant does not meet the requirements for a permit within 1 year after the date on which the application was submitted, the applicant must submit a new application and pay the required fee to be considered for a permit.

5. An application for a permit must be submitted for each location of the outpatient facility where a service of general anesthesia, conscious sedation or deep sedation will be offered.

Sec. 10. *1. Upon receipt of a properly completed and notarized application for a permit and the appropriate fee, the Health Division shall conduct an investigation of the applicant and the outpatient facility pursuant to the provisions of NRS 449.446. During the investigation, the Health Division shall determine whether the outpatient facility is in compliance with the provisions of NRS 449.435 to 449.448, inclusive, and sections 3 to 74, inclusive, of this regulation.*

2. Before issuing a permit, the Health Division must receive a satisfactory report of inspection of the outpatient facility from the State Fire Marshal or the local fire department.

Sec. 11. *1. Except as otherwise provided in subsection 2, a permit is valid for 1 year after the date of issuance, and the holder of the permit may apply for renewal of the permit pursuant to section 12 of this regulation.*

2. A permit is invalid on the date on which the holder of the permit fails to:

(a) Obtain accreditation as required by NRS 449.442 and section 13 of this regulation within 6 months after the date of issuance of the permit;

(b) Maintain current accreditation; or

(c) Provide a report from a nationally recognized organization for accreditation as required by section 13 of this regulation.

Sec. 12. *1. Except as otherwise provided in subsection 3, a holder of a permit to operate an outpatient facility who wishes to renew the permit must submit a completed application for renewal to the Health Division, on a form prescribed by the Health Division, not later than 45 days before the date on which the permit expires. In addition to the annual inspection required by NRS 449.446, the Health Division may require an inspection of the outpatient facility to ensure that it meets the requirements of NRS 449.435 to 449.448, inclusive, and sections 3 to 74, inclusive, of this regulation before deciding whether to renew a permit.*

2. An applicant for the renewal of a permit to operate an outpatient facility must pay to the Health Division a nonrefundable fee of $1,785.

3. A holder of a permit who, without good cause, files an application for the renewal of a permit after the date set forth in subsection 1 but before the expiration of the permit must pay, in addition to the renewal fee for the permit prescribed in subsection 2, a fee equal to one-half the amount of the fee required for the renewal of the permit pursuant to that subsection.

4. A holder of a permit who fails to file an application for the renewal of the permit before the permit expires is not eligible to renew the permit and, if he or she wishes to be permitted, must submit an application for a new permit pursuant to section 9 of this regulation.

Sec. 13. *1. An outpatient facility shall:*

(a) Not later than 6 months after obtaining a permit, submit proof to the Health Division of accreditation by a nationally recognized organization approved by the Board pursuant to subsection 3; and

(b) Maintain current accreditation during the term of the permit.

2. An outpatient facility shall provide to the Health Division each report provided by the accrediting organization, including, without limitation, the initial report, each report issued upon renewal of an accreditation and any other report issued by the accrediting organization.

3. An organization that accredits outpatient facilities and which wishes to be recognized by the Board as an accrediting organization for the purposes of this section must submit to the Health Division an application on a form prescribed by the Health Division. The Health Division shall review each application received pursuant to this subsection and shall forward to the Board each application and the recommendation of the Health Division that the Board approve or not approve the organization as an accrediting organization for purposes of this section. The recommendation of the Health Division must be based upon whether the applicant requires an outpatient facility to meet the minimum requirements necessary to ensure a high level of quality. The Board may approve or deny an application for recognition as an accrediting organization submitted pursuant to this subsection.

4. The Health Division shall maintain on its Internet website a list of all accrediting organizations approved by the Board pursuant to this section.

Sec. 14. ***1. Upon receipt of a permit, the holder shall display the permit at a conspicuous location within the outpatient facility.***

2. During the term of the permit, the outpatient facility shall continuously maintain the facility in conformance with the provisions of NRS 449.435 to 449.448, inclusive, and sections 3 to 74, inclusive, of this regulation.

3. If there is a transfer of the real property on which the outpatient facility is located, but no change in the operator of the outpatient facility, the holder of a permit shall, within 10 days after the transfer, notify the Health Division of the transfer in writing and provide the Health Division with a copy of any lease agreement relating to the transfer.

4. The holder of a permit shall notify the Health Division immediately of any change in the ownership of, location of or services provided by the outpatient facility.

Sec. 15. *In addition to the grounds set forth in NRS 449.447 and section 44 of this regulation, the Health Division may deny an application for a permit or may suspend or revoke a permit upon any of the following grounds:*

1. Misappropriation of the property of a patient of the outpatient facility.

2. Abuse, neglect or exploitation of a person who is infirm, a person with mental retardation, a person with a disability or a person who is 60 years of age or older.

Sec. 16. *As used in sections 16 to 34, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 17 to 26, inclusive, of this regulation have the meanings ascribed to them in those sections.*

Sec. 17. *"Biologic indicator test" means a test used in every ethylene oxide cycle and in every sterilization load of implantable devices to demonstrate through the destruction of highly resistant bacterial spores whether all parameters, including, without limitation, time, temperature, sterilant and humidity, were met to effectively sterilize the medical items.*

Sec. 18. *"Cleaning" means the physical removal of organic material or soil from objects by using water, with or without detergents, that is designed to remove, rather than kill, microorganisms.*

Sec. 19. *"High-level disinfection" means a type of disinfection which destroys all microorganisms with the exception of high levels of bacterial spores. Such disinfection may be accomplished through the use of processes that include, without limitation, boiling items in water, steaming items in water and soaking items in chemical disinfectants.*

Sec. 20. *"Implantable device" means a medical device that is implanted in the human body, including, without limitation, a pacemaker, defibrillator, heart valve, hearing device or joint replacement.*

Sec. 21. *"Invasive procedure" means a medical procedure involving entry into the human body by puncture or incision or by insertion of an instrument.*

Sec. 22. *"Low-level disinfection" means a type of disinfection which eliminates most bacteria, some viruses and some fungi, but which may not kill resistant microorganisms. Such disinfection may be accomplished through the use of processes that include, without limitation, soaking items in chemical disinfectants.*

Sec. 23. *"Multidose vial" means a vial, including, without limitation, a sealed sterile vial, which may be accessed by insertion of a needle and which, according to the manufacturer's instructions:*

1. Contains more than one dose of a medication; and

2. May be used for one or more patients.

Sec. 24. *"Reprocess" means the process of subjecting a single-use medical device that has been previously used on a patient to additional cleaning, disinfection or sterilization,*

manufacturing steps, including, without limitation, repackaging and relabeling, and testing of the technical and functional safety of the device to make the device ready for safe use on another patient.

Sec. 25. *"Single-dose vial" means a vial, including, without limitation, a sealed sterile vial, which may be accessed by insertion of a needle and which, according to the manufacturer's instructions:*

1. Contains only one dose of a medication; and

2. May be used for only one patient.

Sec. 26. *"Sterilization" means a process using medical equipment, including, without limitation, a dry heat sterilizer or an autoclave, to destroy all forms of microbial life.*

Sec. 27. *1. The holder of a permit issued pursuant to section 9 of this regulation shall adopt guidelines which must be used by the outpatient facility in establishing the program for the prevention and control of infections and communicable diseases required by section 28 of this regulation.*

2. The guidelines adopted pursuant to subsection 1 may include, without limitation, guidelines, statements or recommendations issued or published by other agencies or organizations, and must:

(a) Be based on evidence, theoretical rationale or scientific data; and

(b) Include well-designed experimental, clinical or epidemiological studies which document the processes used in the development of the studies and which grade the strength of the evidence relied on in the studies.

3. The holder of the permit shall ensure that a copy of the guidelines adopted pursuant to subsection 1 is available at the outpatient facility and accessible to the staff of the outpatient facility and the public.

Sec. 28. *1. Each outpatient facility shall establish and maintain a program for the prevention and control of infections and communicable diseases.*

2. In addition to complying with the provisions of sections 27 to 33, inclusive, of this regulation, a program for the prevention and control of infections and communicable diseases must be:

(a) Appropriate for the services provided at the outpatient facility;

(b) Based on the guidelines adopted by the holder of the permit pursuant to section 27 of this regulation; and

(c) Developed in a manner that takes into consideration:

(1) All surgical and other medical services provided at the outpatient facility;

(2) The types of patients typically treated at the outpatient facility, including, without limitation, those whose age or medical condition makes them vulnerable to infections and communicable diseases;

(3) The types of injuries or illnesses typically treated at the outpatient facility;

(4) The number of patients typically treated at the outpatient facility;

(5) The level of education and training of the staff of the outpatient facility;

(6) The number of nurses available at the outpatient facility, the qualifications of such nurses and the amount of support required of the nurses by the physicians at the outpatient facility, if applicable;

(7) The types of invasive procedures performed at the outpatient facility;

(8) The locations within the outpatient facility where invasive procedures are performed;

(9) The specific medical instruments and equipment used at the outpatient facility;

(10) The physical design of the outpatient facility; and

(11) The causes, risks and patterns of infections and transmission of communicable diseases that arise in the setting of each medical procedure performed at the outpatient facility.

Sec. 29. *Each program for the prevention and control of infections and communicable diseases must include policies and procedures to prevent exposure to blood-borne and other potentially infectious pathogens, including, without limitation, policies and procedures relating to:*

1. Hand hygiene, including provisions regarding the time and procedure for hand washing with soap and water or the use of an alcohol-based hand rub.

2. The proper use of medical gloves, including, without limitation, a requirement that each person who works at the outpatient facility must wear medical gloves when the person:

(a) Anticipates coming in contact with blood or bodily fluids;

(b) Handles contaminated instruments, items and equipment;

(c) Handles biological waste or biologically contaminated waste that may cause harm to humans, animals or plants;

(d) Handles linens potentially contaminated with biological waste or biologically contaminated waste that may cause harm to humans, animals or plants; and

(e) Performs housekeeping activities or cleans contaminated surfaces.

3. Safe injection practices to prevent the contamination of equipment used for injections and medication, including, without limitation, a requirement that a new sterile needle and new sterile syringe be used for each patient and not used for more than one patient.

4. The proper handling of sharp instruments and the disposal of sharp instruments, which must be consistent with the standards developed by the Occupational Safety and Health Administration of the United States Department of Labor for the handling and disposal of such instruments.

5. Techniques for accessing a vial of medication, which must comply with the requirements set forth in section 30 of this regulation.

6. The infusion of intravenous medications, which must provide, without limitation, that intravenous tubing and fluid bags or bottles are not to be used for more than one patient.

7. The proper sterilization and disinfection of all medical equipment, instruments and devices. Those policies and procedures must, at a minimum, require the outpatient facility to:

(a) Sterilize or ascertain the sterility of items that enter sterile tissue or the vascular system, including, without limitation, surgical instruments, endoscopes, endoscopic accessories, catheters, needles and probes used for ultrasounds;

(b) Perform high-level disinfection of reusable items that come in contact with nonintact skin or mucous membranes, including, without limitation, respiratory therapy equipment, anesthesia equipment, bronchoscopes and gastrointestinal endoscopes; and

(c) Perform low-level disinfection of reusable items that come in contact with only intact skin, including, without limitation, tourniquets, blood pressure cuffs, linens, stands that are used to hold medical instruments and other furnishings.

8. The proper handling of equipment, instruments and devices. Those policies and procedures must, at a minimum, require the outpatient facility to:

(a) Sterilize and disinfect reusable items as described in subsection 7;

(b) Properly dispose of single-use equipment, instruments and devices after use, if the outpatient facility has decided not to have the equipment, instruments or devices reprocessed; and

(c) Ensure that:

(1) All equipment, instruments and devices that may be reprocessed are reprocessed only by a third-party processor approved by the United States Food and Drug Administration; and

(2) No equipment, instruments or devices that may be reprocessed are reprocessed at the outpatient facility.

9. The proper handling and disposal of medical waste and specimens.

10. The proper cleaning and disinfection of all areas in which patient care is provided.

11. The proper maintenance of a clean and sanitary environment.

12. The identification and reporting of the development and transmission of infections and communicable diseases, including, without limitation, the method by which the outpatient facility must:

(a) Track and document the development and transmission of infections and communicable diseases which are related to the medical procedures performed at the outpatient facility;

(b) Report the development and transmission of infections and communicable diseases as required by federal, state and local laws; and

(c) Identify and address trends in such developments and transmissions of infections and communicable diseases.

13. The care of patients with a communicable disease, including, without limitation, patients who are known to have a communicable disease at the time of arrival at the outpatient facility and patients who are found to have a communicable disease during the course of treatment at the outpatient facility.

14. The screening for communicable diseases as described in NAC 441A.375 of all employees and of all persons under contract with the outpatient facility who work at the facility and have exposure to patients at the facility.

Sec. 30. *1. Each program for the prevention and control of infections and communicable diseases must include policies and procedures for single-dose vials which provide that a single-dose vial may be accessed only by using an aseptic technique. The policies and procedures must provide that:*

(a) Each injection of a medication from a single-dose vial must be prepared in a clean, designated area where contamination by blood or bodily fluid is unlikely to occur;

(b) The medication in a single-dose vial must not be used for more than one patient;

(c) A single-dose vial, including any remaining medication in the vial after its use, must be discarded; and

(d) Any remaining medication in a single-dose vial after its use must not be combined with any other medication or otherwise used for any other patients.

2. Each program for the prevention and control of infections and communicable diseases must include policies and procedures for multidose vials which provide that a multidose vial

may be accessed only by using an aseptic technique. The policies and procedures must provide that:

(a) The cap of a multidose vial must be cleaned with an alcohol-based wipe before the vial is accessed;

(b) A new sterile needle and new sterile syringe must be used each time to access a multidose vial;

(c) Upon first access of a multidose vial, the person who accessed the vial shall date and initial the vial;

(d) Each injection of a medication from a multidose vial must be prepared in a clean, designated area where contamination by blood or bodily fluid is unlikely to occur;

(e) A needle must not be left inserted in the cap of a multidose vial after its use; and

(f) A multidose vial must be discarded when the medication in the vial has expired or 28 days after the vial was initially accessed.

Sec. 31. *1. All surgical instruments, items or equipment used in the care of patients at an outpatient facility must be sterilized or disinfected according to the program for the prevention and control of infections and communicable diseases adopted by the outpatient facility pursuant to section 28 of this regulation.*

2. If such instruments, items and equipment are sterilized or disinfected by equipment or cleaning agents at the outpatient facility:

(a) Before an employee or independent contractor may be assigned the responsibility for sterilizing or disinfecting any instrument, item or equipment, the employee or independent contractor must receive training concerning the instructions of the manufacturer of the device or sterilizer for:

(1) Sterilizing and disinfecting the instrument, item or equipment;

(2) The use and maintenance of the sterilizer or disinfecting equipment; and

(3) The agents used to sterilize and disinfect the instrument, item or equipment.

(b) An employee or independent contractor assigned the responsibility for sterilizing or disinfecting the instrument, item or equipment shall:

(1) Receive annual training concerning the manufacturer's instructions described in paragraph (a); and

(2) Receive training on any new equipment or procedures if there is any change in the equipment or procedures used to sterilize or disinfect an instrument, item or equipment.

(c) The outpatient facility shall ensure that documentation of all training completed pursuant to this subsection is kept in the file of the employee or independent contractor.

3. The manufacturer's instructions for operating any sterilizer or performing any disinfection procedure must be located or posted near the equipment used for sterilization or disinfection.

4. The outpatient facility shall ensure that each employee or independent contractor follows the manufacturer's instructions concerning:

(a) The instruments, items or equipment that may be sterilized or disinfected;

(b) The procedures for cleaning an instrument, item or equipment before the instrument, item or equipment is sterilized or undergoes high-level disinfection;

(c) The procedures for sterilizing or disinfecting an instrument, item or equipment;

(d) The operation and maintenance of the sterilizer or the equipment used for high-level disinfection;

(e) The frequency and type of biologic indicator testing of the sterilizer;

(f) The recommended agents for sterilizing and disinfecting the instrument, item or equipment; and

(g) The frequency of testing of any solution for disinfecting to ensure maintenance of the minimum level of effectiveness, but the solution must be tested not less often than daily.

5. The effectiveness of the sterilization procedures must be checked by performing a biologic indicator test:

(a) At least weekly, or more frequently if recommended by the manufacturer; and

(b) While sterilizing all implantable devices.

6. Sterilization records and logs of the results of the biologic indicator test must be maintained by the outpatient facility for at least 1 year after the test is performed to ensure that the recommended testing and maintenance of the equipment is performed and the manufacturer's instructions regarding proper sterilization techniques are followed. Each outpatient facility shall establish a method to track and recall instruments, items or equipment previously sterilized or disinfected if there is a failure of the biologic indicator test.

7. To aid in environmental control, each outpatient facility shall provide a physical barrier between the decontamination and sterilization areas of the outpatient facility.

Sec. 32. *1. Each outpatient facility shall designate an employee or enter into a contract with a person to oversee and manage all aspects of the program for the prevention and control of infections and communicable diseases.*

2. The person described in subsection 1:

(a) Must have completed specialized training in the prevention and control of the development and transmission of infections and communicable diseases; and

(b) Shall ensure that the program for the prevention and control of infections and communicable diseases for the outpatient facility:

(1) Complies with all applicable federal, state and local laws;

(2) Is consistent with the guidelines adopted by the holder of the permit pursuant to section 27 of this regulation; and

(3) Is reviewed with all employees of the outpatient facility and all persons under contract with the outpatient facility who work at the facility and have exposure to patients at the facility within the first 10 days of employment and every 12 months thereafter, or more often if required pursuant to subsection 2 of section 33 of this regulation.

Sec. 33. *1. Each employee of an outpatient facility and each person under contract with an outpatient facility who works at the facility and has exposure to patients at the facility shall receive training and must be evaluated by supervising staff on the employee's or contractor's knowledge and skills concerning the program for the prevention and control of infections and communicable diseases within the first 10 days of employment and at least every 12 months thereafter.*

2. An employee or person under contract with the outpatient facility may be required to receive the training and evaluation described in subsection 1 more often than every 12 months if a supervisor determines that such training and evaluations are necessary to ensure that the employee or contractor understands and will follow the policies and procedures of the program for the prevention and control of infections and communicable diseases.

Sec. 34. *In addition to the guidelines established pursuant to section 27 of this regulation, the holder of a permit to operate an outpatient facility shall establish guidelines and maintain policies for the outpatient facility which:*

1. Ensure the health, safety and well-being of patients of the outpatient facility;

2. Provide the professional standards of practice for services provided by the outpatient facility and ensure that all persons employed by the outpatient facility or under contract with the outpatient facility comply with such professional standards; and

3. Require each person employed by the outpatient facility or under contract with the outpatient facility to have a skin test for tuberculosis in accordance with NAC 441A.375.

Sec. 35. *As used in sections 35 to 74, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 36 to 42, inclusive, of this regulation have the meanings ascribed to them in those sections.*

Sec. 36. *"Cluster" means a deficiency that involves the same or similar kinds of care, treatment or services as one or more other deficiencies.*

Sec. 37. *"De minimis deficiency" means a deficiency rated at a severity level of one or two and at a scope level of one or two.*

Sec. 38. *1. "Deficiency" means noncompliance with any state statute or regulation of the Board. The term includes an incident concerning an outpatient facility where there are no extenuating circumstances or where the facility has made an inappropriate response to a complaint, including the failure to:*

(a) Prevent an incident from occurring, if the incident could have been avoided;

(b) Identify an incident;

(c) Take action to correct an incident before the identification of the incident by the Bureau; or

(d) Implement a contingency plan if permanent action to correct an incident has not been undertaken.

2. In determining whether an incident is a deficiency, the right of the patient to refuse treatment, when applicable, shall be deemed an extenuating circumstance.

Sec. 39. *"Immediate and serious threat" or "immediate jeopardy" means a situation in which corrective action within 48 hours is necessary because the failure by an outpatient facility to comply with a requirement of statute or regulation has caused, or if uncorrected is likely to cause, serious injury or harm, or even death, to a patient.*

Sec. 40. *"Incident" means an action, practice or situation that appears to be inconsistent with a state statute or regulation of the Board.*

Sec. 41. *"Initial deficiency" means the first occurrence of a deficiency recorded by the Bureau, including, without limitation, any deficiency found during a standard inspection, during an extended inspection or in response to a complaint.*

Sec. 42. *"Severity and scope score" means the sum of the numerical levels of severity and scope assigned to a deficiency.*

Sec. 43. *The purposes of administrative sanctions are to:*

1. Safeguard the rights, interests and well-being of patients, including the protection of patients from actual or potential harm resulting from deficiencies; and

2. Encourage and assist outpatient facilities to comply with the requirements of the Health Division.

Sec. 44. *In accordance with NRS 449.447, the Health Division may deny an application for a permit or may suspend or revoke a permit upon any of the following grounds:*

1. Offering to a patient a service of general anesthesia, conscious sedation or deep sedation without a permit, if a permit is required pursuant to NRS 449.435 to NRS 449.448, inclusive, and section 9 of this regulation.

2. The failure or refusal of the holder of a permit to return an adequate plan of correction to the Health Division within 10 days after the receipt of a statement of deficiencies compiled pursuant to NRS 449.446.

3. The failure or refusal of the entity to whom a permit has been issued to comply with a directed plan of correction issued by the Bureau.

4. The failure or refusal to cooperate fully with an investigation or inspection by the Bureau.

Sec. 45. *Administrative sanctions authorized by NRS 449.447 may be imposed by the Health Division through the Bureau.*

Sec. 46. *An applicant or holder of a permit who is aggrieved by an action of the Health Division relating to the denial, suspension or revocation of a permit or any other sanction assessed pursuant to sections 35 to 74, inclusive, of this regulation may appeal pursuant to the procedures set forth in NAC 439.300 to 439.395, inclusive.*

Sec. 47. *1. The Bureau shall impose at least one sanction listed in NRS 449.447 upon an outpatient facility that has a deficiency with a severity level of four or a combined severity and scope score of six or more.*

2. More than one sanction may be imposed at the discretion of the Bureau.

3. The Bureau may impose sanctions if deficiencies of a severity level of three or less or a combined severity and scope score of less than six are identified.

4. If the Bureau chooses to impose a particular sanction, it must be applied according to the severity and scope factors established in sections 50 to 53, inclusive, of this regulation.

Sec. 48. *1. Except as otherwise provided in this section, the Bureau shall give notice pursuant to the provisions of NAC 439.300 to 439.395, inclusive, before taking disciplinary action against an outpatient facility.*

2. If necessary to protect the public health and safety, the Bureau may impose such sanctions as are necessary without notice to the outpatient facility or by oral notice to the outpatient facility.

3. If there is an immediate and serious threat to the health and safety of patients served by an outpatient facility, the provisions concerning notice contained in this section govern.

4. The Bureau may suspend the permit of an outpatient facility without notice or upon oral notice if the Bureau finds that an emergency has caused a deficiency with a severity and scope score of five or more which places one or more patients in immediate jeopardy. For purposes of this subsection, "emergency" means any situation in which an outpatient facility is unable to operate in a safe manner, including, without limitation, due to a fire, flood, contagious infection, loss of utilities or inappropriate transfer of patients.

5. In any case where sanctions are imposed without written notice, the Bureau shall provide written notice that complies with the requirements of NAC 439.345 within 48 hours after the imposition of the sanctions.

Sec. 49. *1. The Bureau may apply one or more sanctions on the basis of deficiencies found during inspections or investigations of complaints conducted by the Bureau.*

2. Deficiencies must be reported to the outpatient facility by the Bureau. The notice to the outpatient facility must specify the deficiencies found and the severity and scope score for each deficiency determined by the Bureau.

3. Any deficiency for which a severity and scope score is not specified is presumed to be a de minimis deficiency.

Sec. 50. *1. In determining the scope of a violation, an inspection of an outpatient facility must evaluate a representative sample of patients as provided in this section. Unless a sample of a different size is required for the inspection by federal law, the sample must consist of at least the following size:*

Number of patients offered a service of general anesthesia, conscious sedation or deep sedation	*Minimum number of such patients in sample*
1 - 9	*All patients*
10 - 40	*10*
41 - 75	*15*
76 - 100	*20*
101 - 175	*25*
176 - 250	*30*
251 - 350	*35*
351 - 450	*40*
451 or more	*50*

2. The sample size used in identifying the scope of a deficiency in a subsequent inspection conducted to evaluate compliance with a plan of correction must not be less than 60 percent of the sample size used in the initial inspection.

3. In determining the scope of a violation involving particular kinds of care, treatment or services, the inspection must evaluate a representative sample of patients receiving or requiring the particular kinds of care, treatment or services. Unless a sample of a different size is required for the inspection by federal law, the sample must consist of at least the following size:

Number of patients needing or receiving a particular kind of care, treatment or services	*Minimum number of such patients in sample*
1 - 9	*All patients*
10 - 40	*10*
41 - 75	*15*
76 - 100	*20*
101 - 175	*25*
176 - 250	*30*
251 - 350	*35*
351 - 450	*40*
451 or more	*50*

4. The Bureau may review more than the minimum number of patients. If it does so, the determination of scope must be based on the number of patients actually reviewed.

5. If the Bureau investigates a complaint relating to a patient, the Bureau may sample only that patient. The scope of any deficiency cited pursuant to this subsection must be scope level one.

6. As used in this section, "patient" means a person who was offered a service of general anesthesia, conscious sedation or deep sedation at the outpatient facility within the 30 days immediately preceding the date the Bureau inspects the outpatient facility.

Sec. 51. *1. The scope scale must be used to assess the scope of a particular deficiency in or by the outpatient facility.*

2. The basis for the assessment is the actual or potential harm to patients as shown by:

(a) The frequency of the deficiency;

(b) The number or percentage of patients affected;

(c) The number or percentage of staff involved; and

(d) The pattern or lack of pattern of the deficiencies.

Sec. 52. *1. The scope of the deficiencies must be evaluated using the criteria prescribed in this section.*

2. A deficiency of scope level one consists of one or an isolated number of unrelated incidents. A deficiency is of this scope if it involves 20 percent or less of the patients sampled in an outpatient facility.

3. A deficiency is scope level two if the Bureau identifies a pattern of incidents at the outpatient facility, including any deficiencies involving patients who require particular kinds of care, treatment or service. The number or percentage of patients or staff involved in the incidents or the repeated occurrences of incidents in short succession may also establish a pattern by indicating a reasonable degree of predictability of similar incidents. A deficiency is

also of this scope if it involves more than 20 percent but not more than 50 percent of the patients sampled in an outpatient facility.

4. A deficiency is of scope level three if it occurs in a sufficient number or percentage of patients or staff or with sufficient regularity over time that it may be considered systemic or pervasive in or by the outpatient facility. A deficiency is also of this scope if it involves more than 50 percent of the patients sampled in an outpatient facility.

Sec. 53. *1. The severity scale must be used to assess the severity of a particular deficiency pertaining to the outpatient facility. The basis for the assessment must be the actual or potential harm to patients.*

2. Deficiencies of severity level one concern requirements promulgated primarily for administrative purposes. No harm is likely to occur to a patient. No negative patient impact has occurred or is likely to occur. The ability of a patient to achieve the highest practicable physical, mental or psychosocial well-being has not been and is not likely to be compromised.

3. Deficiencies of severity level two indirectly threaten the health, safety, rights, security, welfare or well-being of a patient. A potential for harm, as yet unrealized, exists. If continued over time, a negative impact on one or more patients or a violation of one or more patients' rights would occur or would be likely to occur or the ability of one or more patients to achieve the highest practicable physical, mental or psychosocial well-being would be, or would likely be, compromised.

4. Deficiencies of severity level three create a condition or incident in the operation or maintenance of an outpatient facility that directly or indirectly threatens the health, safety, rights, security, welfare or well-being of one or more patients. A negative impact on the health, safety, rights, security, welfare or well-being of one or more patients has occurred or can be

predicted with substantial probability to occur, or the ability of patients to achieve the highest practicable physical, mental or psychosocial well-being has been or is about to be compromised and requires intervention and correction of the deficiency. Failure to implement a directed plan of correction is presumed to be a deficiency of this level of severity.

5. Deficiencies of severity level four create a condition or incident that has resulted in or can be predicted with substantial probability to result in death or serious harm to a patient. As used in this subsection, "serious harm" includes serious mental harm, serious impairment of bodily functions, serious dysfunction of any bodily organ or part, life-threatening harm or death.

Sec. 54. *If the same deficiency is found during a subsequent inspection conducted to evaluate compliance with a plan of correction, there is a rebuttable presumption that the deficiency continued through the period between the inspection and the subsequent inspection. A sanction may be imposed for a subsequent deficiency only if the subsequent inspection is made and the deficiency is again actually found to be present.*

Sec. 55. *The sanctions available for all outpatient facilities include:*

1. The assessment of monetary penalties; and

2. The denial, suspension or revocation of the permit for the outpatient facility.

Sec. 56. *To determine the appropriate sanction, the Bureau shall follow the procedures set forth in sections 35 to 74, inclusive, of this regulation.*

Sec. 57. *The Bureau shall initially assess individual deficiencies or clusters of deficiencies according to the following initial factors:*

1. The presence or absence of an immediate and serious threat to the health and safety of patients;

2. The severity of the deficiency; and

3. The scope of the deficiency.

Sec. 58. *After the initial assessment, the Bureau shall consider the following secondary factors in determining the sanction to impose:*

1. The relationship of one deficiency or cluster or pattern of deficiencies to other deficiencies;

2. The history of previous compliance by the outpatient facility generally and specifically with reference to the deficiencies in issue;

3. Whether the deficiencies are directly related to the care, services or treatment received by patients who were offered a service of general anesthesia, conscious sedation or deep sedation by the outpatient facility; and

4. The corrective and long-term compliance outcomes desired.

Sec. 59. *1. The selection of a sanction must be based upon the nature of the deficiencies or cluster of deficiencies and the sanction most likely to correct those deficiencies.*

2. Absent evidence to the contrary, monetary penalties are presumed to be the most effective sanctions for deficiencies that do not cause an immediate and serious threat to patients.

3. The Bureau may impose a monetary penalty alone or in addition to other penalties.

Sec. 60. *1. The outpatient facility shall develop a plan of correction for each deficiency and submit the plan to the Bureau for approval within 10 days after receipt of the statement of deficiencies compiled by the Health Division pursuant to NRS 449.446. The plan of correction must include specific requirements for corrective action, which must include times within which the deficiencies are to be corrected.*

2. If the plan is not acceptable to the Bureau, the Bureau may:

(a) Direct the outpatient facility to resubmit a plan of correction;

(b) Develop a directed plan of correction with which the outpatient facility must comply; or

(c) Revoke the outpatient facility's permit.

3. Failure to submit the plan of correction to the Bureau within 10 days after receipt of the statement of deficiencies constitutes a separate deficiency subject to monetary penalties with severity and scope rated at the same levels as the highest deficiency identified on the notice of deficiencies.

Sec. 61. *1. Except as otherwise provided in subsection 4, the Bureau may impose a monetary penalty including interest thereon on any outpatient facility that is not in compliance with a requirement of NRS 449.435 to 449.448, inclusive, and sections 3 to 74, inclusive, of this regulation, regardless of whether the deficiency constitutes an immediate and serious threat.*

2. If a monetary penalty is imposed, the initial amount of the penalty must be based on the severity and scope score of the deficiency and must be imposed as provided in section 64 of this regulation.

3. In addition to the initial monetary penalty, the Bureau may impose a monetary penalty for each day of noncompliance from the date the noncompliance occurs or is identified until compliance is verified.

4. An outpatient facility is not subject to a monetary penalty for a de minimis deficiency.

Sec. 62. *1. The Bureau shall impose an initial monetary penalty pending a hearing or appeal. The payment of the initial penalty must not be stayed during the pendency of any administrative appeal.*

2. The payment of any daily monetary penalties or interest that accrues while the outpatient facility has a hearing pending on the initial determination of deficiencies leading to the imposition of sanctions must be stayed pending the appeal.

Sec. 63. *1. If the Bureau imposes a monetary penalty, the penalty must be imposed as provided in sections 63 to 67, inclusive, of this regulation.*

2. In imposing the monetary penalty, the total penalty assessed against any facility bears interest at the rate of 10 percent per annum on the unpaid balance of the penalty, beginning on the due date.

Sec. 64. *1. In determining the amount of an initial monetary penalty, the Bureau shall consider the severity alone if the severity level is four. In determining the amount of the monetary penalty where the severity level is less than four, both severity and scope must be considered. In determining whether to impose a daily monetary penalty, the Bureau shall consider the severity and scope and the factors indicated for increased and decreased penalties provided in sections 65 and 67 of this regulation.*

2. For initial deficiencies with a severity level of four, an initial monetary penalty of $1,000 per deficiency must be imposed.

3. For initial deficiencies rated with a severity level of three and a scope level of three, a monetary penalty of $800 per deficiency must be imposed.

4. For initial deficiencies with a severity level of three and a scope level of two or less, an initial monetary penalty of $400 per deficiency must be imposed.

5. For initial deficiencies with a severity level of two and a scope level of three, an initial monetary penalty of $200 per deficiency may be imposed. The payment of this monetary

penalty must be suspended if the outpatient facility has corrected the deficiencies within the time specified in the plan of correction approved by the Bureau.

6. In addition to any monetary penalty imposed pursuant to this section, the Bureau may impose a monetary penalty of not more than $1,000 per deficiency per day for each day the deficiency continues.

Sec. 65. *1. Penalties must be increased for repeated deficiencies or if compliance is falsely alleged.*

2. For each repeat deficiency present within 18 months after an initial deficiency, the monetary penalty must be computed at the rate of one and one-half times the rate that was or could have been assessed initially for a deficiency of that severity and scope, not to exceed $1,000 per deficiency per day.

3. The Bureau may double the daily monetary penalty, not to exceed $1,000 per deficiency per day, that was or could have been assessed if the outpatient facility alleges compliance and the Bureau finds during an inspection that, at the time compliance was alleged, the deficiencies continued to exist.

Sec. 66. *There is a rebuttable presumption that deficiencies identified on a subsequent inspection conducted to evaluate compliance with a plan of correction were present on each day between the date of the initial deficiency and the date the subsequent deficiency was found in the subsequent inspection.*

Sec. 67. *If an outpatient facility against which a monetary penalty is imposed:*

1. Waives the right to a hearing;

2. Corrects the deficiencies that were the basis for the sanction; and

3. Pays the monetary penalty within 15 days after receipt of the notice of the penalty,

➥ the penalty must be reduced by 25 percent, and no interest may be charged.

Sec. 68. *The effective beginning date of a daily monetary penalty is:*

1. In the case of an immediate and serious threat, the date the deficiency occurred; or

2. In any other case, the day the deficiency is identified.

Sec. 69. *1. Daily penalties and interest must be computed after compliance has been verified or the outpatient facility has been sent notice of termination of a permit. A daily monetary penalty must end on the effective date of compliance or termination of the permit of the outpatient facility.*

2. If an outpatient facility achieves compliance, the Bureau shall send a separate notice to the outpatient facility containing:

(a) The amount of the penalty per day;

(b) The number of days involved;

(c) The due date of the penalty; and

(d) The total amount due.

3. If the permit of an outpatient facility is to be terminated, the Bureau shall send the information required by subsection 2 in the notice of termination.

4. If the Bureau's decision of noncompliance is upheld on appeal or the outpatient facility waives its right to a hearing, the monetary penalty must be imposed for the number of days between the effective date of the penalty and the date of correction of the deficiencies or, if applicable, the date the permit of the outpatient facility is terminated.

Sec. 70. *1. The daily accrual of a monetary penalty must end if the outpatient facility demonstrates that deficiencies have been corrected and that the health, safety and well-being of patients are adequately protected and safeguarded.*

2. A monetary penalty may be imposed on a daily basis for not longer than 6 months, after which the Bureau shall deny, suspend or revoke the permit of the outpatient facility.

3. If the outpatient facility can supply credible evidence that substantial compliance with requirements was attained on a date preceding that of the inspection, monetary penalties accrue only until that date of correction for which there is credible evidence. As used in this subsection, "credible evidence" means actual documentation that compliance has been achieved.

Sec. 71. *1. Initial monetary penalty assessment payments are due within 15 days after the notice of the penalty and must be paid irrespective of any administrative appeal.*

2. The daily monetary penalty is due and must be paid within 15 days after compliance is verified or termination of a permit is effective and the outpatient facility is notified of the amount of the total daily monetary penalty and interest due.

3. If the outpatient facility has appealed a decision imposing a monetary penalty, the daily penalty is due and must be paid after the final administrative decision is rendered and 15 days after the outpatient facility has been notified of the amount of the total daily penalty and interest due.

Sec. 72. *Any expenses incurred by the Bureau or the Health Division in implementing and enforcing administrative sanctions, bringing an action in a course of competent jurisdiction for enforcement or collecting any monetary penalty may be recovered from the outpatient facility, including, without limitation, attorney's fees, filing fees, fees for service of notices or process and all expenses of litigation recoverable as costs pursuant to chapter 18 of NRS.*

Sec. 73. ***1. If the outpatient facility fails to pay a monetary penalty, the Health Division may suspend the permit of the outpatient facility.***

2. The Health Division shall, in accordance with the requirements of NAC 439.345, provide notice of its intention to suspend the permit of the outpatient facility.

3. If the outpatient facility fails to pay the monetary penalty, including any expenses set forth in section 72 of this regulation, in collection of the penalty, within 10 days after receipt of the notice, the Health Division shall suspend the permit of the outpatient facility. The suspension must not be stayed during the pendency of any administrative appeal.

Sec. 74. ***Money collected by the Health Division as administrative sanctions must be deposited into a separate fund and applied to the protection of the health, safety, rights, welfare and well-being of patients.***

Sec. 75. NAC 449.002 is hereby amended to read as follows:

449.002 As used in ~~[this chapter,]~~ ***NAC 449.002 to 449.99939, inclusive,*** unless the context otherwise requires, the words and terms defined in NAC 449.0022 to 449.0072, inclusive, have the meanings ascribed to them in those sections.

Sec. 76. NAC 449.0028 is hereby amended to read as follows:

449.0028 "Bureau" means the Bureau of ~~[Licensure and Certification]~~ ***Health Care Quality and Compliance*** of the Health Division.

HEALTH DIVISION
Bureau of Health Care Quality and Compliance
Health Facilities Program
June 18, 2010
LCB File # R179-09

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.

Before drafting the regulations, the agency met with stakeholder groups. Then draft regulations were developed and all offices of physicians (registering with their boards as using sedation in the treatment of their patients) were mailed a copy of the proposed draft regulations along with a small business impact questionnaire. The mailing also identified the date, time and place for the public workshop. The public workshops were properly noticed in accordance with open meeting requirements and all interested parties were given an opportunity to provide comments before, during and after the public workshops which occurred in September of 2009. After the workshops the agency accepted written comments until a final draft of the regulations was provided to LCB. Minutes from the public workshops are attached.

2. The number of persons who:
   (a) Attended the hearing;
   (b) Testified at each hearing; and
   (c) Submitted to the agency written statements.

The number of persons who attended the June 18, 2010 hearing
Las Vegas = 52
Carson City = 55
Testified = 7
The number of persons who attended the public workshops:
Las Vegas = 17
Carson City = 12
The number of persons who testified at the public workshops:
Las Vegas = 9
Carson City = 3
The number of person who submitted written statements to HCQC = 4

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.

All offices of physicians (registering with their boards as using sedation in the treatment of their patients) were mailed a copy of the proposed draft regulations along with a small business impact questionnaire. Responses to the small business impact questionnaire were summarized and a small business impact statement was generated, copy of that summary is attached.

Interested individuals may contact the Bureau of Health Care Quality and Compliance to obtain a copy of the summary.

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.

The proposed regulation was adopted with only a minimal change according to errata that was submitted.

The Institute for Medical Quality asked to be added to the list of approved accrediting organizations. Instead of listing certain organizations and therefore endorsing private organizations within the regulations, a more fair and equitable process was determined which mirrors the process for new organizations developed for the ambulatory surgery centers. The difference for outpatient settings is that all of the accrediting organizations will need to go through an approval process with the BOH in order to be put on the list of accrediting organizations, whereas for ASCs, only new organizations, not already recognized by the Board must go through the approval process.

The Nevada Health Care Association asked for clarification on the exception discussed in NRS 449.441. We discussed this with our Legislative Counsel Bureau drafter and it was determined that we should not attempt to clarify the statutory exemptions in regulation, but must instead allow the respective physician boards to determine whether a physician is administering medication only to relieve anxiety or pain that is not in a dosage sufficient to induce a controlled state of depressed consciousness similar to sedation.

A physician was concerned that it is cost prohibitive to have to meet accreditation requirements. The language in the statutes is clear, both a state permit is required and accreditation with a nationally recognized organization. So this concern can only be addressed with the legislature.

Representatives from outpatient settings were concerned that some surgeries are performed in the absence of sedation, using topical or local anesthetic and these settings will not be regulated. In consultation with our LCB drafter it was determined that the statutes did not give us authority to regulate facilities based on whether surgery is performed, but rather only based on whether sedation is used. The language in the statutes is clear, so this concern can only be addressed with the legislature.

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
   (b) Both immediate and long term effects.

Estimated economic effect:

(a) BHCQC has determined that the adoption of these regulations will create an economic impact on outpatient settings, because they establish new fees. BHCQC has attempted to minimize this

affect by initially setting fees at half the cost of similar facilities for initial licensure and renewal. These fees will be evaluated during the next biennium to determine whether they are sufficient to cover the cost of agency services. The regulations will have an economic effect on small businesses. Initial licensure fees have been set at $3,570 and renewal fees at $1,785, for outpatient settings. The regulations will impose a burden upon small businesses, but will not 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."

(b) The proposed regulations should have a beneficial effect on the public. They specify requirements with foundation in the accrediting organizations that have for many years

established credibility in the health care industry. These new regulations also build regulatory framework to ensure that outpatient settings meet minimum provisions to ensure patient safety and promote infection control.

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

A fiscal note attached to AB 123 during the legislative session estimated the cost to BHCQC at $257,236 in the 2009-2010 fiscal year and $442,403 in the 2010-2011 fiscal year. These costs included 2.0 FTE in 2009-2010 for outpatient settings and 1.0 FTE in 2010-2011 for outpatient settings. The costs also included 1.0 FTE in 2009-2010 for surgery centers and .5 FTE in 2010-2011 for surgery centers. So there's a total of 4.5 FTE between the two facility types for the two fiscal years. Out of the 4.5 FTE, 1.5 FTE are associated with surgery centers and 3.0 FTE are associated with outpatient settings. Or approximately 33.3% of the costs are associated with surgery centers and 66.6% of the costs are associated with outpatient settings. So for 2009-2010 the additional cost for outpatient settings would be $171,319 and for 2010-2011 the additional cost for outpatient settings would be $294,640.

These costs were based on rudimentary analysis of the legislation and associated workload. The fees within the regulations were established to offset the cost of the workload for outpatient settings and will be adjusted based on actual costs.

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.

These regulations do not represent duplication on local or federal levels. The Nevada State Board of Health is responsible for generating regulations for this facility type and there is no equivalent responsibility on the local or federal level.

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

There are no federal regulations that regulate 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.

The total amount anticipated to be collected in 2009-2010 fiscal year is $224,910 (approx. 25% of the total possible applicants are anticipated to apply in this period (63 X 3,570 = 224,910). The total amount anticipated to be collected in 2010-2011 fiscal year is $581,910 (another 65% of the total possible applicants are anticipated to apply in this period (163 X 3,570 = 581,910). We anticipate that 10% of the total possible applicants may elect not to become permitted. Money collected will be used to process applications, conduct surveys and complaint investigations in outpatient settings and unlicensed facilities.

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?

All offices of physicians (registering with their boards as using sedation in the treatment of their patients) were mailed a copy of the proposed draft regulations along with a small business impact questionnaire. It was determined that adoption of these regulations will create an economic impact on outpatient settings, because they establish new fees, but will not directly restrict the formation, operation, or expansion of a small business in Nevada. BHCQC has attempted to minimize this affect by initially setting fees at half the cost of similar facilities for initial licensure and renewal. These fees will be evaluated during the next biennium to determine whether they are sufficient to cover the cost of agency services.

SMALL BUSINESS IMPACT STATEMENT

Outpatient Settings

PROPOSED REGULATIONS for Outpatient Settings have been developed by the Bureau of Health Care Quality and Compliance (BHCQC).

BHCQC is required by Assembly Bill 123 of the 2009 legislative session to generate regulations for the permitting of outpatient settings. These regulations were developed with the intent to meet the requirements of the legislation and to promote quality health care provision in safe environments.

The proposed regulations should have a beneficial effect on the public. They specify requirements with foundation in the accrediting organizations that have for many years established credibility in the health care industry. These new regulations also build regulatory framework to ensure that outpatient settings meet minimum provisions to ensure patient safety and promote infection control.

BHCQC has determined that the adoption of these regulations will create an economic impact on outpatient settings, because they establish new fees. BHCQC has attempted to minimize this affect by initially setting fees at half the cost of similar facilities for initial licensure and renewal. These fees will be evaluated during the next biennium to determine whether they are sufficient to cover the cost of agency services. The regulations will impose a burden upon small businesses, but will not 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 and an explanation of the manner in which other interested parties may obtain a copy of the summary.**

Comments have been solicited by mailing notifications and small business impact questionnaires to physicians identified as using sedation in the treatment of patients. These notifications were mailed on September 1, 2009 with a deadline for response of September 21, 2009. All physicians identified as using sedation in the treatment of patients were provided a questionnaire (See attachment #A) to allow them to express their concerns over the economic impact of these proposed regulations on their businesses. Nevada currently has approximately 250 licensed physicians using sedation in the treatment of patients. Almost all of these physician offices meet the statutory definition of a small business, because they employ less than 150 employees. Only 11 physician offices responded to the questionnaire.

Copies of the summaries of these questionnaires are available from the office of the Bureau of Health Care Quality and Compliance, 4220 South Maryland Parkway, Building D, Suite 810, Las Vegas, Nevada 89119. (702) 486-6515.

2. The estimated economic effect of the proposed regulation on the small business which it is to regulate including without limitation both adverse and beneficial effects.

The regulations will have an economic effect on small businesses. Initial licensure fees have been set at $3,570 and renewal fees at $1,785, for outpatient settings.

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

The BHCQC provided questionnaires as well as forums for health care providers to comment and reviewed the suggestions for changes that would lessen the economic impact. The BHCQC has attempted to minimize the economic impact during the biennium, by setting the fees at half the cost of similar facilities. During the biennium BHCQC will determine actual costs associated with permitting and complaint investigation for outpatient settings.

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

A fiscal note attached to AB 123 during the legislative session estimated the cost to BHCQC at $257,236 in the 2009-2010 fiscal year and $442,403 in the 2010-2011 fiscal year. These costs included 2.0 FTE in 2009-2010 for outpatient settings and 1.0 FTE in 2010-2011 for outpatient settings. The costs also included 1.0 FTE in 2009-2010 for surgery centers and .5 FTE in 2010-2011 for surgery centers. So there's a total of 4.5 FTE between the two facility types for the two fiscal years. Out of the 4.5 FTE, 1.5 FTE are associated with surgery centers and 3.0 FTE are associated with outpatient settings. Or approximately 33.3% of the costs are associated with surgery centers and 66.6% of the costs are associated with outpatient settings. So for 2009-2010 the additional cost for outpatient settings would be $171,319 and for 2010-2011 the additional cost for outpatient settings would be $294,640.

These costs were based on rudimentary analysis of the legislation and associated workload. The fees regulations are being amended to establish new fees that will offset the cost of the workload for outpatient settings.

5. If the proposed regulation provides a new fee or increases an existing fee, the total annual amount the agency expects to collect and the manner in which the money will be used.

The total amount anticipated to be collected in 2009-2010 fiscal year is $224,910 (approx. 25% of the total possible applicants are anticipated to apply in this period (63 X 3,570 = 224,910). The total amount anticipated to be collected in 2010-2011 fiscal year is $581,910 (another 65% of the total possible applicants are anticipated to apply in this period (163 X 3,570 = 581,910). We anticipate that 10% of the total possible applicants may elect not to become permitted. Money collected will be used to process applications, conduct surveys and complaint investigations in outpatient settings and unlicensed facilities.

6. If the proposed regulation includes provisions which duplicate or are more stringent than federal, state or local standards regulating the same activity, an explanation of why such duplicative or more stringent provisions are necessary.

These regulations do not represent duplication on local or federal levels. The Nevada State Board Of Health is responsible for generating regulations for this facility type and there is no equivalent responsibility on the local or federal level.

Summary of Responses:

Question: Will a specific regulation have an adverse economic effect upon your business?
(a) 7 yes
(b) 4 no

Question: Will the regulation(s) have any beneficial effect upon your business?
(a) 1 yes
(b) 9 no
(c) 1 left blank

Question: Do you anticipate any indirect adverse effects upon your business?
(a) 5 yes
(b) 5 no
(c) 1 left blank

Question: Do you anticipate any indirect beneficial effects upon your business?
(a) 0 yes
(b) 10 no
(c) 1 left blank

Please see attachment with summary of comments.