PROPOSED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R052-02

June 12, 2002

EXPLANATION - Matter in *italics* is new; matter in brackets formitted material is material to be omitted.

AUTHORITY: §§1-14 and 16, NRS 449.037; §15, NRS 449.037, 449.068 and 449.069; §17, NRS 449.037 and 449.050.

- **Section 1.** Chapter 449 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 15, inclusive, of this regulation.
- Sec. 2. "Facility for refractive laser surgery" has the meaning ascribed to it in NRS 449.00387.
- Sec. 3. As used in sections 3 to 15, inclusive, of this regulation, unless the context otherwise requires, "facility" means a facility for refractive laser surgery as defined in NRS 449.00387.
- Sec. 4. Sections 3 to 15, inclusive, of this regulation do not apply to an ophthalmologist or group of ophthalmologists licensed pursuant to chapter 630 of NRS or a doctor of osteopathy licensed pursuant to chapter 633 of NRS who provides other ophthalmological medical services in addition to the evaluation of refractive errors of the eye and the surgical treatment of patients by photorefractive keratectomy or laser in situ keratomeleusis.
- Sec. 5. 1. A licensee of a facility shall appoint an administrator to be legally responsible for:
 - (a) The daily operation of the facility; and
 - (b) Compliance with the applicable provisions of this chapter and chapter 449 of NRS.

- 2. The administrator of a facility must:
- (a) Be at least 21 years of age;
- (b) Have at least 1 year of administrative experience in a health care setting;
- (c) Have experience in the administration and supervision of personnel; and
- (d) Possess such knowledge of the practice of medicine as to enable him to be conversant in surgical protocols.
- Sec. 6. If a licensee leases a laser or other equipment to another ophthalmologist for the surgical treatment of patients by photorefractive keratectomy and laser in situ keratomeleusis, the licensee remains responsible for the services performed by the other ophthalmologist in the facility.
 - Sec. 7. The administrator of a facility shall ensure that:
 - 1. The facility is adequately staffed with qualified personnel who:
 - (a) Meet the needs of and ensure the safety of each person who visits the facility; and
 - (b) Satisfy any applicable statutory requirements for the provision of care.
- 2. Each member of the staff who provides patient care is adequately trained in emergency procedures and is currently certified to perform first aid and cardiopulmonary resuscitation.

 At least one member of the staff who is trained in emergency procedures and who has obtained the advanced certificate in first aid and adult cardiopulmonary resuscitation issued by the American Red Cross or an equivalent certification must be in the facility whenever patients are present in the facility.
- 3. A separate personnel file is established and maintained for each member of the staff of the facility that includes:

- (a) Proof of any training relating to emergency response required by the facility pursuant to the policies and procedures established by the facility pursuant to section 9 of this regulation;
- (b) Such health records as are required by chapter 441A of NAC which include evidence that the member of the staff employed by the facility or under contract with the facility has had a skin test for tuberculosis in accordance with NAC 441A.375; and
- (c) Evidence that the member of the staff employed by the facility or under contract with the facility has obtained any license, certificate or registration, and possesses the experience and qualifications, required for the position held by that person.
- Sec. 8. 1. The administrator of a facility shall ensure that the facility establishes and maintains a record of each patient admitted to the facility which includes an assessment of the health needs of the patient and a description of any health care services provided to the patient at the facility.
 - 2. Each record must be:
 - (a) Protected against loss, destruction or unauthorized use;
 - (b) Kept confidential, except as otherwise provided by law; and
- (c) Maintained for a period of 5 years after the date the patient is discharged from the facility.
- 3. If the facility closes, the administrator shall notify the bureau of the disposition of its records.
- Sec. 9. 1. The administrator of a facility shall ensure that the facility has written policies and procedures available to members of the staff, patients and the public which govern the operation of the facility and services provided by the facility.

- 2. The policies and procedures must set forth, without limitation:
- (a) The scope of services offered by the facility, the cost of those services and the procedures for the payment of fees and obtaining a refund of any deposited fees;
- (b) The business hours of the facility and the care that is available at the facility during emergencies and after the normal business hours of the facility;
 - (c) The criteria for admission to and discharge from the facility;
- (d) The qualifications required for each member of the staff of the facility and the scope of the duties of each member of the staff of the facility;
- (e) The appropriate action to be taken when an emergency arises in the facility and the equipment and medication that is required to be available at the facility for such an emergency;
- (f) The manner in which the equipment and physical environment of the facility will be maintained in accordance with the requirements set forth in sections 11 and 12 of this regulation;
 - (g) The conduct and responsibility of a patient relating to his treatment;
 - (h) The right of a patient to refuse to participate in experimental research;
 - (i) The procedure for filing a complaint or grievance at the facility;
 - (j) The rights of a patient and the procedure for informing each patient of his rights;
 - (k) The manner in which the records of a patient will be maintained and protected; and
- (l) The manner in which medication will be administered and dispensed to a patient admitted to the facility in accordance with the laws of this state and federal law.
 - **Sec. 10.** The administrator of a facility shall ensure that:
 - 1. Each patient admitted to the facility is treated with respect, consideration and dignity.

- 2. Each patient admitted to the facility is provided appropriate privacy.
- 3. Each patient admitted to the facility is informed of his rights as a patient in accordance with the provisions of NRS 449.730. The patient must be informed, at the time of his admission, of the services available, the estimated cost of those services and the policy of the facility relating to obtaining a refund of any fees that were deposited with the facility. If a patient is unable to understand his rights, they must be explained to his legal guardian, next of kin or the agency financially responsible for his care.
- 4. Each patient admitted to the facility is given the opportunity to participate in decisions relating to his health care, unless he is unable to do so because of his medical condition.
- 5. An informed consent properly executed by a patient admitted to the facility or by his legal guardian is obtained before any surgery is performed. The informed consent must authorize, by name, the person performing the surgery to perform that surgery and must name or describe the surgical procedure to be performed. Any expectations, risks or complications relating to the surgery or alternatives to the surgery that are discussed with the patient must be set forth in the informed consent.
 - **Sec. 11.** 1. The administrator of a facility shall ensure that:
 - (a) The facility is adequately equipped;
- (b) Any equipment used in the facility is periodically inspected and, if appropriate, tested, calibrated, serviced or repaired according to the manufacturer's instructions to ensure that the equipment is functioning properly;
- (c) All equipment and supplies used in the facility are used in accordance with the manufacturer's instructions;

- (d) Such records are maintained as required to ensure that appropriate inspections and maintenance of all equipment used in the facility are periodically accomplished by an appropriately qualified person;
- (e) Each laser used in the facility meets the requirements of any applicable federal standards set forth in 21 C.F.R. Part 1040; and
- (f) Appropriate evidence of compliance with 21 C.F.R. Part 1040 is maintained for each laser at the facility.
- 2. The administrator of the facility shall ensure that policies and procedures are established and implemented for each laser used in the facility which include, without limitation:
 - (a) A safety program concerning the use of the laser; and
- (b) Education and training of each person who operates the laser, including, without limitation, requirements that each member of the staff be adequately trained in the use and safety of each laser used in patient care and that the administrator ensure that proof of any required training is maintained at the facility.
- 3. The administrator of the facility shall ensure that a safe environment for the use of lasers is provided, including, without limitation, ensuring that:
 - (a) Only authorized persons are allowed in treatment areas;
 - (b) Door and window coverings are used where appropriate;
 - (c) Protective eyewear is used, when appropriate, by persons who operate a laser;
- (d) Laser components which have direct contact with a patient are appropriately disinfected or sterilized;
 - (e) Records concerning the maintenance of each laser in the facility are maintained; and

- (f) Each laser in the facility is visually inspected and tested before each use.
- 4. The administrator of the facility shall ensure that appropriate fire protection concerning the use of each laser is provided, including, without limitation, the immediate availability of:
- (a) Fire extinguishers which are inspected at least once a year and determined to be appropriate for electrical fires by a person who is certified by the state fire marshal to conduct such inspections;
 - (b) Water for the protection of the patient; and
 - (c) Noncombustible materials, supplies and solutions, as appropriate.
- Sec. 12. 1. The administrator of a facility shall ensure that all parts of the facility, including its premises and equipment, are maintained in a neat and clean condition which is free of insects, rodents, litter and rubbish. Policies and procedures must be established and implemented for cleaning, sanitizing or sterilizing equipment and supplies.
- 2. The administrator of the facility shall ensure that the facility has a clean, comfortable waiting room with adequate space for any family member or caregiver of the patient being treated. A separate bathroom must be maintained for the exclusive use of patients and their family members or caregivers. Provisions for the safe storage of valuables must be made available for the use of the patient.
- 3. The operating room must be distinctly separate and segregated from any other area, including, without limitation, the waiting room, examination room, administrative area, physician's office and staff lounge.
- 4. The facility must have sufficient space for the care and storage of instruments and supplies.

- 5. The facility must have adequate systems for ventilation and the control of temperature.
- 6. All medications must be stored, administered and maintained in accordance with the requirements of the laws of this state and federal law.
- Sec. 13. The administrator of a facility shall ensure that the facility has a program of quality improvement in place which:
 - 1. Monitors and evaluates the quality of patient care;
 - 2. Evaluates methods to improve patient care;
 - 3. Identifies and corrects deficiencies; and
- 4. Reviews and resolves grievances of patients and maintains documentation of the resolutions of those grievances.
 - Sec. 14. 1. The administrator of a facility shall ensure that:
- (a) Only local anesthesia and oral medication which is administered to a patient to relieve anxiety in the patient, if the medication is not given in a dosage which is sufficient to induce in a patient a controlled state of depressed consciousness or unconsciousness similar to the state produced pursuant to the administration of general anesthesia, deep sedation or conscious sedation, are used at the facility.
- (b) An appropriate and current history including a list of current medications, dosages, physical examination and pertinent preoperative diagnostic studies is incorporated into the patient's medical record before surgery.
- (c) Surgical procedures are performed only by an ophthalmologist licensed pursuant to chapter 630 of NRS or a doctor of osteopathy licensed pursuant to chapter 633 of NRS.

- (d) A preoperative evaluation is conducted by the ophthalmologist, licensed pursuant to chapter 630 of NRS, or the doctor of osteopathy, licensed pursuant to chapter 633 of NRS, who will be performing the surgery immediately before the procedure.
- (e) Emergency equipment and medications as required by the policies and procedures established by the facility pursuant to section 9 of this regulation are available, and properly stored and maintained at the facility.
- (f) Outdated medications are destroyed in accordance with the requirements of the laws of this state and federal law.
- (g) Protocols are established and implemented for instructing patients in self-care after surgery, including, without limitation, written instructions to be given at the time of discharge.
- (h) A follow-up examination of a patient is conducted by an ophthalmologist licensed pursuant to chapter 630 of NRS, a doctor of osteopathy licensed pursuant to chapter 633 of NRS or a collaborating optometrist as provided in NRS 636.374 within 24 hours after the procedure. Documentation of the results of this examination must be included as part of the permanent medical record of the patient.
 - 2. As used in this section:
- (a) "Conscious sedation" means a minimally depressed level of consciousness, produced by a pharmacologic or nonpharmacologic method or a combination thereof, in which the patient retains the ability independently and continuously to maintain an airway and to respond appropriately to physical stimulation and verbal commands.
- (b) "Deep sedation" means a controlled state of depressed consciousness, produced by a pharmacologic or nonpharmacologic method or a combination thereof, and accompanied by a

partial loss of protective reflexes and the inability to respond purposefully to verbal commands.

- Sec. 15. 1. A person who has sustained damages as a result of the bankruptcy of or any breach of contract by a facility may file an application for indemnification with the administrator of the health division. The administrator of the health division shall return an incomplete application to the applicant.
- 2. An application filed pursuant to subsection 1 must include a copy of the court order or settlement agreement which indicates a determination that the patient sustained damages as a result of a breach of contract or bankruptcy of a facility and a notarized statement of the patient or patient's legal representative which includes the following information:
- (a) A brief description of the damages sustained by the patient as a result of the bankruptcy of or any breach of contract by the facility;
 - (b) The date that the damages were sustained and the amount of damages claimed; and
 - (c) The name and address of the facility in which the patient sustained damage.
- 3. The health division may bring an action for interpleader against all claimants upon the surety bond or substitute thereof filed or deposited pursuant to NRS 449.068 or 449.069, as applicable. If the health division brings such an action, the health division shall publish notice of the action at least once each week for 2 weeks in a newspaper of general circulation in the county in which the facility has its principal place of business. The health division may deduct its costs of the action, including the costs of publication of the notices, from the amount of the surety bond or substitute thereof.

- 4. All claims against the surety bond or substitute thereof have equal priority. If the surety bond or substitute thereof is insufficient to pay all the claims in full, the claims must be paid pro rata.
- 5. If no claims have been filed against the surety bond or substitute thereof deposited with the health division within 12 months after the license of the facility expires or is revoked, the health division shall release the surety bond or substitute thereof to the facility and shall not consider any claim filed by a patient against the surety bond or substitute thereof after that time.
- 6. If one or more claims have been filed against the surety bond or substitute thereof within 12 months after the license of the facility expires or is revoked, the proceeds must not be released to the facility or distributed to any patient earlier than 18 months after the license of the facility expires or is revoked.
 - **Sec. 16.** NAC 449.012 is hereby amended to read as follows:
- 449.012 As used in NAC 449.012 to 449.0168, inclusive, *and section 2 of this regulation*, unless the context otherwise requires, the words and terms defined in NAC 449.0121 to 449.0127, inclusive, *and section 2 of this regulation* have the meanings ascribed to them in those sections.
 - **Sec. 17.** NAC 449.013 is hereby amended to read as follows:
- 449.013 1. Except as otherwise provided in NAC 449.0168, an applicant for a license to operate any of the following facilities, programs of hospice care or agencies must pay to the health division the following nonrefundable fees:
 - (a) An ambulatory surgical center.....\$1,200

((c) A home office or subunit agency of a home health agency	1,200
((d) A branch office of a home health agency	500
((e) A rural clinic	1,200
((f) An obstetric center	1,200
((g) A program of hospice care	1,200
((h) An independent center for emergency medical care	1,200
((i) A nursing pool	750
((j) A facility for treatment with narcotics	750
((k) A medication unit	500
((l) A referral agency	750
((m) A halfway house for recovering alcohol and drug abusers	500
((n) A facility for refractive laser surgery	3,545
2	2. An applicant for the renewal of such a license must pay to the health division the	
following nonrefundable fees:		
((a) An ambulatory surgical center	\$600
((b) A facility for the treatment of irreversible renal disease	600
((c) A home office or subunit agency of a home health agency	600
((d) A branch office of a home health agency	100
((e) A rural clinic	600
((f) An obstetric center	600
((g) A program of hospice care	600
((h) An independent center for emergency medical care	600
((i) A nursing pool	600

(j) A facility for treatment with narcotics	600
(k) A medication unit	100
(l) A referral agency	600
(m) A halfway house for recovering alcohol and drug abusers	300
(n) A facility for refractive laser surgery	3,000

3. An application for a license is valid for 1 year after the date on which the application is submitted. If an applicant does not meet the requirements for licensure imposed by chapter 449 of NRS or the regulations adopted pursuant thereto within 1 year after the date on which he submits his application, he must submit a new application and pay the required fee to be considered for licensure.