

**LCB File No. R042-06**

**PROPOSED REGULATION OF THE  
STATE BOARD OF HEALTH**

**FACILITIES FOR REFRACTIVE LASER SURGERY**

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

The following sections have not been revised or modified: NAC 449.4504, 449.4508, 449.451, 449.4512, 449.4514, 449.4516, 449.4518, 449.4522, 449.4524, and 449.4526

**Section 1.** Chapter 449 of NAC is hereby amended by adding thereto the provisions set forth as section 2, inclusive, of this regulation.

**Sec. 2** *If a facility for refractive surgery performs intraocular lens implants it must:*

- 1. Ensure that equipment and supplies are sufficient so that the intraocular lens implant can be performed in a manner that will not endanger the health and safety of the patient;*
- 2. Ensure that all individuals in the surgical area conform to aseptic technique;*
- 3. Provide suitable equipment for the rapid and routine sterilization of operating room materials;*
- 4. Develop appropriate protocols for the procedure that include a list of equipment, materials, and supplies necessary to properly carry out the procedure;*
- 5. Develop protocols for the provision of services in case of emergency and ensure that all personnel are appropriately trained;*
- 6. Only a registered nurse may function as a circulating nurse in the operating room.*

**Sec. 3.** NAC 449.450 is hereby amended to read as follows:

7 449.450 “Facility” defined. (NRS 449.037) As used in NAC 449.450 to 449.4526, unless the context otherwise requires, “facility” means a facility for refractive ~~[laser]~~ surgery as defined in NRS 449.00387.

**Sec. 4.** NAC 449.4502 is hereby amended to read as follows:

449.4502 Applicability of provisions. (NRS 449.037) NAC 449.450 to 449.4526, inclusive, do not apply to an ophthalmologist 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; ~~laser~~ laser in situ keratomeleusis~~is~~; *Conductive keratoplasty; Implantation of an intraocular lens; and any other available technology, technique or procedure which surgically treats refractive errors of the eye and which has been approved by the United States Food and Drug Administration.*

**Sec. 5.** NAC 449.4506 is hereby amended to read as follows:

449.4506 Staffing requirements; personnel files. (NRS 449.037) 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 facility shall employ at least one full time registered nurse licensed pursuant to NRS 632 to supervise and manage the care provided to patients in the facility.*

*3. There must be at least one registered nurse present in the facility whenever patients are present in the facility.*

~~2~~ 4. 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~~ 5. 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 NAC 449.451;

(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.

## SMALL BUSINESS IMPACT STATEMENT

### FACILITIES FOR REFRACTIVE LASER SURGERY

PROPOSED REVISION TO REGULATIONS for Facilities for Refractive Laser Surgery. The regulations may impose a burden upon small businesses and may 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.

#### BACKGROUND

Due to concerns of irregular business practices of freestanding refractive surgery centers, the 2001 legislative session through SB 483 required the licensure of Facilities for Refractive Laser Surgery. At that time, the law was written to only require licensure for facilities providing laser in situ keratomeleusis (LASIK) and photo refractive keratectomy (PRK). The 2005 session removed the word “Laser” from the definition of the facility and expanded the definition to include conductive keratoplasty and implantation of intraocular lenses. It also would include any new technology, technique or procedure which has been approved by the United States Food and Drug Administration. This change could potentially require the licensure of facilities that previously had not met the statutory definition. The changes to the regulations also require the facilities to employ at least one full time registered nurse.

#### **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.**

The 1999 legislature amended Nevada Revised Statutes (NRS) Chapter 233B to require that state agencies assess the impact of regulation changes or development on small businesses. In keeping with this requirement, all licensed facilities and all of the members of the Nevada Ophthalmological Society were provided with a questionnaire to assess the impact of these changes on their businesses and a copy of the draft regulations. A total of thirty-two (32) questionnaires were sent out and three (3) were returned.

The comments received are summarized as follows:

Two (2) questionnaires were returned indicating the changes to the regulations would have no adverse or beneficial effects on the business.

One respondent stated that the requirement to employ at least one full time registered nurse (RN) and have at least one RN present in the facility when patients are present would have an adverse economic effect on the business and would be difficult to fulfill due to the shortage of registered nurses across the country.

Copies of the summaries of these questionnaires are available from the office of the Bureau of Licensure and Certification 1550 E. College Parkway, Suite 158, Carson City, Nevada 89706 (775) 687-4475 and 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 beneficial effect of these regulations is to insure uniform quality and safety of care and to establish a level of quality control that would be standard for all facilities. The adverse economic effect would be the licensure fees and the surety bond required by the law. The regulations do not impact currently licensed physicians or Doctors of Osteopathy who provide other ophthalmological medical services in addition to LASIK or PRK.

**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 agency reviewed the suggestions for changes that would lessen the economic impact. Wherever possible, in keeping with existing state laws, these changes have been made.

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

**The estimated cost to the agency for each facility is \$7,556. This includes surveyor time, supervisory time, and clerical time. Renewal fees are currently set at \$3,912.**

**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.**

Since July of 1993, all state licensure activities have been supported by fees charged to those health facilities seeking licensure. The agency expects to collect \$7,356 for each Facility for Refractive Surgery. The money will be utilized to cover the cost of agency time to educate of providers, the clerical and supervisory time required to complete the application process, the surveyor time and supervisory time for inspection, and the clerical time required to issue the license.

**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.**

There are no existing state or federal regulations for facilities for Refractive Surgery.