ADOPTED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R042-06

Effective July 14, 2006

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

AUTHORITY: §§1-6, NRS 449.037.

A REGULATION relating to facilities for refractive surgery; revising provisions concerning the health and safety of patients; revising provisions governing the exemption of ophthalmologists and doctors of osteopathy from provisions governing such facilities; and providing other matters properly relating thereto.

Section 1. Chapter 449 of NAC is hereby amended by adding thereto a new section to read as follows:

The administrator of a facility that performs intraocular lens implants shall:

- 1. Ensure that equipment and supplies are sufficient so that intraocular lens implants are performed in a manner that will not endanger the health and safety of the patient;
 - 2. Ensure that all persons in the surgical area use aseptic techniques;
- 3. Provide suitable equipment for the rapid and routine sterilization of operating room materials;
- 4. Develop appropriate protocols that include a list of equipment, materials and supplies necessary to carry out the procedure properly;
- 5. Develop protocols for the provision of services in case of emergency and ensure that all personnel are appropriately trained in those protocols; and
 - 6. Ensure that each circulating nurse in the operating room is a registered nurse.

Sec. 2. NAC 449.01227 is hereby amended to read as follows:

449.01227 "Facility for refractive [laser] surgery" has the meaning ascribed to it in NRS 449.00387.

Sec. 3. 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	\$3,570
(b) A facility for the treatment of irreversible renal disease	2,748
(c) A home office or subunit agency of a home health agency	3,034
(d) A branch office of a home health agency	2,000
(e) A rural clinic	2,160
(f) An obstetric center	1,564
(g) A program of hospice care	2,106
(h) An independent center for emergency medical care	2,950
(i) A nursing pool	4,272
(j) A facility for treatment with narcotics	2,482
(k) A medication unit	1,200
(l) A referral agency	2,000
(m) A halfway house for recovering alcohol and drug abusers	2,020
(n) A facility for refractive [laser] surgery	7,556
(a) A mobile unit	2 000

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\$1,785
(b) A facility for the treatment of irreversible renal disease
(c) A home office or subunit agency of a home health agency
(d) A branch office of a home health agency
(e) A rural clinic 1,080
(f) An obstetric center
(g) A program of hospice care
(h) An independent center for emergency medical care
(i) A nursing pool
(j) A facility for treatment with narcotics
(k) A medication unit
(l) A referral agency 1,000
(m) A halfway house for recovering alcohol and drug abusers
(n) A facility for refractive [laser] surgery
(o) A mobile unit

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.

Sec. 4. NAC 449.450 is hereby amended to read as follows:

- 449.450 As used in NAC 449.450 to 449.4526, *inclusive*, *and section 1 of this regulation*, unless the context otherwise requires, "facility" means a facility for refractive [laser] surgery as defined in NRS 449.00387.
 - **Sec. 5.** NAC 449.4502 is hereby amended to read as follows:
- 449.4502 *The provisions of* NAC 449.450 to 449.4526, inclusive, *and section 1 of this regulation* 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 or laser in situ keratomeleusis.]:
 - 1. Photorefractive keratectomy;
 - 2. Laser in situ keratomeleusis;
 - 3. Conductive keratoplasty;
 - 4. Implantation of an intraocular lens; or
- 5. 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. 6.** NAC 449.4506 is hereby amended to read as follows:
 - 449.4506 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. The facility employs at least one full-time registered nurse licensed pursuant to chapter 632 of NRS to supervise and manage the care provided to patients in the facility.
- 3. At least one registered nurse who is employed by the facility is present in the facility at all times that any patient is present in the facility.
- 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 *present* in the facility whenever [patients are] any patient is 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.

NOTICE OF ADOPTION OF PROPOSED REGULATION LCB File No. R042-06

The State Board of Health adopted regulations assigned LCB File No. R042-06 which pertain to chapter 449 of the Nevada Administrative Code on June 16, 2006.

Notice date: 5/17/2006 Date of adoption by agency: 6/16/2006

Hearing date: 6/16/2006 **Filing date:** 7/14/2006

INFORMATIONAL STATEMENT

1. DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED, SUMMARY OF PUBLIC RESPONSE, AND AN EXPLANATION OF HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

A Small Business Impact Questionnaire was mailed to the Refractive Laser Surgery facilities and Ophthalmologists in Nevada on December 16, 2006. Attachment A is the Small Business Impact Statement Questionnaire. Attachment B is a copy of the Small Business Impact Summary.

Notice of public workshops held on January 12, 2006, in Las Vegas and on January 13, 2006, in Reno was published in the Las Vegas Review Journal and Reno Gazette Journal on or before December 23, 2006. Notices of public workshops, and proposed regulations were mailed to all county libraries in Nevada, Refractive Laser Surgery facilities, Ophthalmologists in Nevada, and interested parties on December 16, 2005. The Small Business Impact Summary was available at both workshops.

There were no written or public comments at the Reno or Las Vegas workshops.

Notice of public hearing regarding the Board's intent to adopt amendments was published in the Las Vegas Review Journal and Reno Gazette Journal on or before May 17, 2006. Notices of public hearing, and proposed regulations were mailed to all county libraries in Nevada Refractive Laser Surgery facilities and Ophthalmologists in Nevada, and interested parties on May 11, 2006. The notice of public hearing was mailed to Southern Nevada Health District and Washoe County District Health Department on May 11, 2006.

Copies of the workshop minutes and Board of Health hearing minutes may be obtained by calling the Bureau of Licensure and Certification at (775) 687-4475.

- 2. THE NUMBER OF PERSONS WHO:
- (A) ATTENDED THE HEARING;

Approximately 133 people attended the June 16, 2006, Board of Health hearing.

(B) TESTIFIED AT EACH HEARING; AND

No one in attendance testified on Refractive Laser Surgery.

(C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

No written statements were submitted.

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

Comment was solicited from affected or potentially affected businesses by mailing appropriate facilities and all interested parties the proposed regulations, a small business impact questionnaire, a copy of the small business impact summary, and the notices for the workshops and Board of Health hearings. Copies of the workshop minutes and Board of Health hearing minutes may be obtained by calling the Bureau of Licensure and Certification at (775) 687-4475.

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.

No testimony was received in opposition to the proposed regulation or which suggested changes to the proposed regulation.

- 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

Anticipated effects on the business which NAC 449 regulates.

Adverse: None Beneficial: None

Anticipated effects on the public:

Adverse: None

Beneficial: All refractive surgery facilities will be regulated.

(B) BOTH IMMEDIATE AND LONG TERM EFFECTS.

Anticipated effects on the business which NAC 449 regulates.

Immediate: None Long-term: None

Anticipated effects on the public:

Immediate: None

Long-term: Provides oversight of refractive surgery facilities.

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

There is no anticipated additional cost to the agency for enforcement of the proposed regulation changes.

7. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH THE PROPOSED REGULATION OVERLAPS OR DUPLICATES AND A STATEMENT EXPLAINING WHY THE DUPLICATION OR OVERLAPPING IS NECESSARY. IF THE REGULATION OVERLAPS OR DUPLICATES A FEDERAL REGULATION, NAME THE REGULATING FEDERAL AGENCY.

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

8. IF THE REGULATION INCLUDES PROVISION WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISION.

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

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 amendments do not establish any new fees or increase any existing fees.