ADOPTED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R052-02

Effective July 24, 2002

EXPLANATION – Matter in ***italics*** is new; matter in brackets ~~[omitted 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 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 immediately before the surgical procedure 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.

(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

(b) A facility for the treatment of irreversible renal disease 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. 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.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R052-02

The Bureau of Licensure and Certification of the Health Division of the Department of Human Resources adopted regulations assigned LCB File No. R052-02 which pertain to refractive laser surgery (chapter 449 of the Nevada Administrative Code) on June 14, 2002.

Notice date: May 14, 2002
Hearing date: June 14, 2002
Date of adoption by agency: June 14, 2002
Filing date: July 24, 2002

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 Facilities for Refractive Laser Surgery on April 1, 2002. Attached is a copy of the Small Business Impact Summary.

Notice of public workshops held on April 24, 2002, in Las Vegas and April 25, 2002, in Reno was published in the Las Vegas Review Journal and Reno Gazette Journal on or before April 8, 2002. Notices of public workshops, and proposed regulations were mailed to all county libraries in Nevada, Facilities for Refractive Laser Surgery, and interested parties on April 1, 2002. The small business impact summary was available at both workshops.

Five individuals provided comments during the workshops. They were generally in agreement with the regulations, however, provided suggestions and changes to the regulations.

Notice of public hearing regarding the Board's intent to adopt amendments was published in the Las Vegas Review Journal, Reno Gazette Journal on or before May 15, 2002. Notices of public hearing, proposed regulations and the small business impact summary was mailed to all county libraries in Nevada, Clark County Health District, Washoe County Health District, Facilities for Refractive Laser Surgery, and interested parties on May 9, 2002.

2. THE NUMBER OF PERSONS WHO:

(A) ATTENDED THE HEARING;

Approximately 32 people attended the June 14, 2002, Board of Health hearing.

(B) TESTIFIED AT EACH HEARING; AND

Jeanette Belz, Nevada Ophthalmological Society
James Summerfelt, St. Mary's Eye Inst.

(C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

No written statements were provided at the hearing.

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 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.

None.

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.

It is anticipated that there will be a beneficial effect on the businesses covered by these regulations. Facilities that provide quality service will have the added benefit of licensure to attest to their compliance with a set standard. Facilities that fall below this standard will be required to bring their services up to a community standard.

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

There will be an economic impact to BLC based on the need for additional surveyor time and provider education.

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. Additionally, there is no overlap or duplication of a federal 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.

None.

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 BLC may receive approximately 10 applications for Facilities for Refractive Laser Surgery within the SFY '03 for a total of approximately $35,000.00. The fees are used to support required state licensure activities, and to administer surety bonds required for this facility type.

SMALL BUSINESS IMPACT STATEMENT
(Nevada Revised Statutes 233B.0608)

FACILITIES FOR REFRACTIVE LASER SURGERY

PROPOSED 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. Under NRS 449.0151 subsection 14 "Medical facility" defined to include a facility for refractive laser surgery. NRS449.068 requires that Facilities for Refractive Laser Surgery file a surety bond with the administrator of the health division when applying for licensure. The legislative intent of SB 483 was, through the licensure process, to create an economic disincentive, for those facilities that do not operate in the best interest of the patient. The purpose of the licensure and the required bond is to provide indemnification to any patient who has sustained damages as a result of the bankruptcy of, or any breach of contract, by the facility. The proposed regulations do not apply to individual opthamologists or groups of opthamologists licensed pursuant to Nevada Revised Statutes 630 or Doctors of Osteopathy licensed pursuant to NRS 633 who provide other opthamological medical services in addition to PRK or LASIK

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, a review of advertising information, yellow pages, and the white pages was conducted both in northern and southern Nevada. All identified facilities were sent a small business impact questionnaire and a copy of the draft regulations to allow them to express their concerns over the economic impact of these proposed regulations on their businesses. In addition, at the request of the Nevada Opthamological Society, all of their members were provided with the questionnaire and a copy of the draft regulations. A total of 84 questionnaires were sent out and 21 were returned. In addition, two parties responded by telephone.

The comments received are summarized as follows:

(a) Six respondents felt that the fees were excessively high in comparison to fees required from other types of facilities. One respondent felt that the fees should not be higher than fees charged to an ambulatory surgical center.
(b) One respondent felt that increased fees would have to be passed on to patients and recommended no fees.
(c) One respondent felt that there was no need to monitor quality because he already did that himself.
(d) One respondent felt that the new rules would increase the possibility of litigation.
(e) One respondent asked that the use of Valium and Xanex type medications be added to the regulations and pointed out that protective eyewear for staff is not necessary with the use of Eximer Lasers.
(f) One respondent suggested that licenses for this type of facility only be given to physicians who had been practicing in Nevada for two or three years.
(g) One respondent was concerned about who would monitor these facilities and felt that only experts in the field of refractive laser surgery were qualified to monitor.
(h) One respondent suggested that a percentage or absolute number of procedures performed would be a better way to determine who is required to be licensed and felt that with the changing nature of laser refractive surgery, limiting the law to apply to LASIK and PRK might make the law ineffective.
(i) Three respondents fully supported the regulations and felt that they will have a generally beneficial effect on the business by establishing a level of quality control.
(j) One respondent felt that the regulations will require refractive surgery to be viewed as a true surgery and the patients will receive the safe, quality care to which they are entitled.
(k) One respondent was concerned that corporate or privately owned centers would be able to find a loophole to the new regulations and felt that the new law was too narrow to protect consumers.
(l) Two respondents felt that quality providers were already following the requirements of the new regulations.
(m) Two respondents commented that some regulation is required to insure quality care.

Copies of the summaries of these questionnaires are available from the office of the Bureau of Licensure and Certification 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 opthamological 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 $3,545. This includes surveyor time, supervisory time, and clerical time.

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 $3,545 for each Facility for Refractive Laser 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 Laser Surgery.