LCB File No. R057-99

NOTICE OF PUBLIC HEARING

NOTICE IS HEREBY GIVEN that the State Health Division will hold public hearing and act on amendments to Nevada Administrative Code (NAC) 445A, 449, 450B and 652. **The hearing is scheduled to begin at 9:00 a.m. on Friday, September 10, 1999, at the Grant Sawyer Building, Room 4410, 555 E. Washington Avenue, Las Vegas, Nevada.**

THIS HEARING IS TO MAKE TEMPORARY REGULATIONS PERMANENT.

RESIDENTIAL FACILITIES FOR GROUPS

In September of 1997 the Temporary Regulations for Residential Facilities for Groups were presented to the Board of Health as a Legislative Counsel Bureau file, for permanent adoption. Between the changes bureau staff proposed to the temporary regulations (after using them for almost one year) and changes that LCB made to the temporary regulations (during their preparation for permanent adoption) some language mistakes occurred and became evident during the past year. In addition the BOH has requested that we modify language at NAC 449.226.4 concerning call systems in large facilities in order to eliminate the need for variances to this particular requirement. The bureau decided it would wait until the regulations were codified by LCB before attempting to change any language.

We have established new language and modifications to existing language in the following areas:
NAC 449.0168, NAC 449.193, NAC 449.200, NAC 449.209, NAC 449.226, NAC 449.229, NAC 449.2704, NAC 449.2742, NAC 449.2744, NAC 449.2746, NAC 449.2749, NAC 449.275, NAC 449.2756, and NAC 449.2764

The changes are not substantial and are designed to clarify issues rather than create more requirements.

The changes present no anticipated effect to the public.

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

The regulations proposed for change will not effect changes to other governmental agencies and do not overlap/duplicate other regulations.

The regulations proposed for change do not overlap/duplicate federal regulations.

The regulations do not have a counterpart in the code of federal regulations.

The regulations will add two new fees to the fee schedule at NAC 449.0168.1, 1) one for

addition or change of facility type endorsements on a license and 2) one for change to the category on a license.

RESIDENTIAL FACILITIES FOR GROUPS - FEES

In September of 1997, the Temporary Regulations for Residential Facilities for Groups were presented to the Board of Health as a Legislative Counsel Bureau file, for permanent adoption. Between the changes bureau staff proposed to the temporary regulations (after using them for almost 1 year) and changes that LCB made to the temporary regulations (during their preparation for permanent adoption) it was identified that some language modification was required in the general provisions section of NAC Chapter 449. The Bureau decided it would wait until the regulations were codified by LCB before attempting to change any language.

In July the bureau received a copy of the codified regulations. The bureau subsequently drafted proposed changes to the regulations and will present these changes before the December BOH meeting.

We have established new language and modifications to existing language in the following areas:

NAC 449.0168

The changes are designed to establish standards for processing applications to change license endorsements, whereas currently there is no authority nor mechanism for the bureau to receive applications for the changes discussed. If the language is modified as presented the industry will benefit from the ability to apply for changes through the formal application process, rather than the current informal process.

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

The regulations proposed for change will not effect changes to other governmental agencies and do not overlap/duplicate other regulations.

The regulations proposed for change do not overlap/duplicate federal regulations.

The regulations do not have a counterpart in the code of federal regulations.

The regulations will add two new fees to the fee schedule at NAC 449.0168.1, 1) a fee for addition or change of facility type endorsements on a license and 2) a fee for change to the category indicated on a license.

SURGICAL CENTERS FOR AMBULATORY PATIENTS

The proposed amendments are needed to update the current regulations originally adopted in 1988 relating to the licensing of surgical centers for ambulatory patients. The amendments also update the construction standards relating to ambulatory surgical centers.

The proposed regulations affect all services/departments in ambulatory surgical centers.

The proposed regulations will have a beneficial effect, recognized by the ambulatory surgical centers industry, on the ambulatory surgical centers because they were developed by utilizing current standards of care that are defined by the Medicare/Medicaid reimbursement participation standard. All currently licensed hospitals meet these standards at this time because all the hospitals participate in the Medicare/Medicaid reimbursement program.

The proposed regulations will have a beneficial effect on the public/consumer by assuring the public, through the state licensure process, that ambulatory surgical centers are meeting current standards of care.

There will be no change in cost to the facilities or to the Bureau of Licensure and Certification (BLC) for the change in the regulations for the licensing of ambulatory surgical centers. The current fee for initial and annual renewal of licenses will cover the cost to BLC.

The proposed regulations state that the facility must be in compliance with Nevada Revised Statutes (NRS) 449.700-449.730, NRS 453, NRS 652.217, and Nevada Administrative Code (NAC) 441 A and NAC 459. The duplication was necessary to assure certain statutes that affect the health and safety of residents and visitors to Nevada are being implemented by ambulatory surgical centers licensed by BLC.

The proposed regulations parallel the federal Medicare/Medicaid reimbursement participatory regulations governing ambulatory surgical centers (42 Code of Federal Regulations (CFR) Part 416, subpart A, B, and C) in certain sections and 42 CFR 489.24, Clinical Laboratory Improvement Amendment of 1988, Public Health Service Act (42 USC 274) and Life Safety Code, Standard 101.

The regulations are more stringent than the Federal regulations governing ambulatory surgical centers in certain areas: regulations for tuberculosis screening in employees, patient rights, and construction standards.

The regulations do not establish new fees or increase an existing fee.

POINT OF CARE TESTING

Proposed changes to Chapter 652 Medical Laboratories are necessary to allow healthcare professionals to perform waived and moderate complexity testing at the bedside in medical facilities licensed pursuant to Chapter 449.

Point of Care testing is defined and point of care device is described with limitations of use.

Qualifications and activities of the point of care analyst are identified and certification fees are

established. Continuing education requirements apply to the point of care analyst.

Anticipated benefits to both laboratories regulated by NAC 652 and the public (the patients) will be an overall cost reduction as a result of decreased length of stay due to rapid return of results to the physician. These benefits are both immediate and long term. There are no adverse effects anticipated.

The increased cost to the agency will be funded by establishing a certification fee issued for point of care testing analyst.

NAC 652 and CLIA regulations (42 CFR Part 493 of the Code of Federal Regulations) have established requirements for the performance of laboratory testing, however, with the recent availability of small portable hand-held analyzers, bedside testing by healthcare professionals other than traditional laboratory technical staff required changes to existing regulations.

HOSPITALS

The proposed amendments are needed to update the current regulations originally adopted in 1969 relating to the licensing of hospitals. The amendments also update the construction standards relating to hospitals.

The proposed regulations affect all services/departments in acute hospitals. Current standards of care for those departments were addressed in the regulations.

The proposed regulations will have little if any effect on the acute hospitals because they were developed by utilizing current standards of care that are defined by the Medicare/Medicaid reimbursement participation standards. All currently licensed hospitals meet these standards at this time because all the hospitals participate in the Medicare/Medicaid reimbursement program.

The proposed regulations will have a beneficial effect on the public/consumer by assuring the public, through the state licensure process, that hospitals are meeting current standards of care.

There will be no change in cost to the facilities or to the Bureau of Licensure and Certification (BLC) for the change in the regulations for the licensing of hospitals. The current fee for initial and annual renewal of licenses will cover the cost to BLC.

The proposed regulations state that the facility must be in compliance with Nevada Revised

Statutes (NRS) 449.700 – 449.730, NRS 439B.410, NRS 652.217, NRS 632, and Nevada

Administrative Code (NAC) 441 A and NAC 459. The duplication was necessary to assure

certain statutes that affect the health and safety of residents and visitors to Nevada are being

implemented by hospitals licensed by BLC.

The proposed regulations parallel the federal Medicare/Medicaid reimbursement participatory

regulations governing acute hospitals (42 Code of Federal Regulations (CFR) Part 482, Subpart A, B, C, and D) in certain sections and 42 CFR 489.24, Clinical Laboratory Improvement Amendment of 1988, Public Health Service Act (42 USC 274) and Life Safety Code, Standard 101.

The regulations are more stringent than the Federal regulations governing hospitals in certain

areas: regulations for tuberculosis screening in employees, certain patient care areas, patient

rights, and construction standards.

SKILLED NURSING REGULATIONS

The proposed amendments are needed to update the current regulations originally adopted in 1969 relating to the licensing of skilled nursing facilities. The amendments also update the construction standards relating to skilled nursing facilities.

The proposed amendments will incorporate resident rights, resident behavior and facility practices, quality of life, resident assessment, and quality of care requirements not included in the current regulations. Additionally, general requirements such as physician, nursing and dietary services will be addressed, as well as construction and design requirements.

The adoption of the proposed amendments should not create an economic or operational impact on licensed facilities because the proposed regulations parallel federal regulations the facilities have been following since 1990.

The proposed amendments are considered to provide a beneficial impact for the public by providing licensing standards for the care, safety and quality of life for nursing home residents consistent with current standards of practice.

The adoption of the proposed amendments should have no economic impact on the Bureau of Licensure and Certification because the proposed regulations parallel federal regulations that the agency has surveyed under contract with the Health Care Financing Administration.

These regulations do not duplicate the regulations of other state or local government entities.

The regulations parallel federal regulations of the Health Care Financing Administration 42

C.F.R. 483.1 through 483.75, inclusive.

The proposed amendments include several sections that are more stringent than the federal regulations: Requirements for design and construction of skilled nursing facilities that are not addressed in federal regulation; requirements for TB testing of personnel.

The proposed amendments do not change existing fees or impose any new fees.

CONSTRUCTION STANDARDS

The proposed amendments are needed to update the current regulations originally adopted in 1969 relating to the construction standards of skilled nursing facilities and hospitals.

The proposed regulations affect all services/departments in acute hospitals.

The proposed regulations will have little effect on existing structures. All new construction and remodeling projects will be required to comply with the guidelines. The guidelines are used nationwide and will be beneficial to facilities in that architects or other design professionals are currently using the same guidelines in other states.

The proposed regulations will be beneficial to the general public by providing a nationally recognized standard for constructing a health care facility in a safe fashion.

There will be no change in cost to the facilities or to the Bureau of Licensure and Certification (BLC) for the change in the regulations for the licensing of hospitals. The current fee for initial and annual renewal of licenses will cover the cost to BLC.

The proposed regulations state that there are satisfactory assurances that the facility meets all applicable Federal, State and local laws and complies with all applicable life safety, environmental health, building and fire codes and zoning ordinances. If there are any differences between the State and local codes, the more restrictive standards apply. This is necessary to inform the facility that they are required to meet other codes or laws to pass the building inspection and zoning or certificate of occupancy requirements.

The proposed regulations reference the National Fire Protection Association (NFPA) as the basic codes of reference, in particular, the Life Safety Code NFPA 101, and the NFPA 99. These particular references and several others are included in "The Guidelines for Design and Construction of Hospitals and Health Care Facilities" on pages 3, 4 and 5.

The proposed regulations are more stringent than the federal regulations at 42 CFR 482.41 Condition of Participation – Physical Environment. This is necessary because the federal regulations do not address design and construction of facilities.

The proposed regulations do not establish new fees or increase an existing fee.

CERTIFICATION OF ENVIRONMENTAL TESTING LABORATORIES

The Administrative Code Chapter 445A pertaining to Certification of Environmental

Laboratories analyzing drinking water in accordance with the Federal Safe Drinking Water Act

as presently constituted has some defects that require resolution. The United States

Environmental Protection Agency along with stakeholders throughout the nation has developed a

consensus standard called the National Environmental Laboratory Accreditation Conference (NELAC) standard. The Bureau of Licensure and Certification has participated in the development of this standard. A program for laboratories to certify according to this nationally accepted standard has been put forth. It is called the National Environmental Laboratory Accreditation Program (NELAP). States may adopt the standard and they may participate in NELAP if they so choose.

Participation in NELAP necessitates subscribing to the NELAC standard which is organized in four distinct tiers, namely: 1.) Legal Identity and Mission; 2.) Testing Capability; 3.) Regulatory Program; 4.) Test Methods.

Each of these "tiers" are addressed in the current NAC but are not organized efficiently and items referenced therein create areas of confusion due to conflicting instructions or protocols. At one juncture the authority to revoke or downgrade certification based upon information obtained from site surveys was denied the Bureau because not all of the pertinent chapters of the referenced standard were included.

Some of the material included in the current NAC, though important, does not apply to laboratory certification. It should be separated from the certification portion of the code.

It is proposed that a completely new version of Chapter 445A pertaining to Environmental Laboratory Certification be adopted in accordance with a template provided by NELAC. This code follows the organizational pattern established by the NELAC standard and includes changes that are required for NELAP participation. Standards that are unique to Nevada will be retained. Since this version is new, the section identification numbers will not coincide with or relate to those of the current code. It is proposed to eliminate the current code and replace it with the new wording. Section numbers can be changed to fit into the surrounding code.

Anticipated effects on the environmental laboratory business are beneficial and immediate. Adoption of this revision will affect environmentally sensitive businesses in the following ways:

1. EPA involvement with the Performance Testing program has been changed. The NAC will reflect these changes.
2. Nevada will be able to participate in the NELAP program if it elects to do so.
3. Ambiguous language will be replaced so consistency in agency action will be assured.
4. Laboratories electing to participate in NELAP accreditation may do so with Nevada as their sponsoring authority.
5. NELAP accredited laboratories will have automatic reciprocity among all NELAP participation states. (So far twenty states have applied for NELAP participation and several more have committed.) *Nevada laboratory certification officers recommend that Nevada participate*.
6. NELAP participating laboratories will be held to a common standard.
7. NELAP participating laboratories will be able to participate in Federal contracts.
8. NELAP participating laboratories will not suffer a competitive disadvantage relative to participants.
9. NELAP participating laboratories will be assured a level playing field nationally.
10 NELAP participating laboratories will produce data of known, consistent and comparable quality.
11. Laboratories not electing NELAP accreditation will not be required to do so, but will be held to the NELAC standard in so far as it is appropriate.
12. Agencies and businesses requiring analyses of regulated parameters will be assured that data meet a rigorous nationally accepted standard.

Anticipated effects on the public are beneficial and long-term. The changes will assist in maintaining quality laboratory analytical capacity to ensure that measurements that affect the public health will be trustworthy.

The estimated cost to the agency for enforcement of the proposed regulation will not be any different than for the current regulation. In the event Nevada elects to have Bureau of Licensure and Certification Laboratory Certification Officers trained to become NELAP assessors, the cost will be limited to the training expense. The training is required every four years.

The regulations do not overlap or duplicate any federal regulations.
The regulations will maintain the existing fee structure.

DEFIBRILLATION - 450B.900-.936 (This regulation does not apply to EMS providers under the authority of Clark County Health District.)

These amendments are to repeal the existing regulations concerning defibrillation, add

defibrillation to the authorized practices of emergency medical technicians, and add the

definitions currently listed in sections .900 thru .914 to the “General Provisions” section of

450B.

This section of NAC 450B was placed in regulation because the use of automatic and semi-automatic defibrillation was introduced as a pilot program for emergency medical technicians and has since become a normal part of the emergency medical technician's scope of practice.

The National Highway Traffic Safety Administration of the United States Department of Transportation has adopted in the EMT Basic program training for the use of automatic and semi-automatic defibrillators. This eliminates the need for further training and certification in defibrillation for the EMT, as currently required in NAC 450B.918-.936.

This section of NAC 450B has generated unnecessary costs and training time for EMS services and personnel.

There are no anticipated effects on the business which NAC 450B regulates.

There are no anticipated effects on the public.

There are no anticipated additional costs to the Health Division for enforcement of the proposed regulation.

There are no existing regulations of other state or local governmental agencies which the proposed amendments to the regulations overlap or duplicate.

DO NOT RESUSCITATE - 450B.955

These amendments are to implement a fee for issuance of a Do Not Resuscitate Identification bracelet. This fee would cover the cost of the bracelet, including engraving and shipping the bracelet to the patient.

There are no anticipated effects on the business which NAC 450B regulates.

There are no anticipated effects on the public.

Estimated cost to the Health Division for enforcement of the proposed regulation:

Expenditure of $1,575.00 for purchasing an initial inventory of bracelets. This expenditure will be recouped in full through a fee to be determined by the health authority.

The amendment establishes a fee determined by the health authority not to exceed the actual cost of obtaining the medallion from a manufacturer, including the cost of engraving, shipping and handling.

There are no existing regulations of other state or local governmental agencies which the proposed amendments to the regulations overlap or duplicate.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence in excess of two typed, 8-1/2" x 11" pages must submit the material to the Board's Secretary by August 26, 1999.

Secretary, State Board of Health
Nevada State Health Division
Capitol Complex
505 E. King Street, Room 201
Carson City, NV 89701-4797

Written comments, testimony, or documentary evidence in excess of two typed pages will not be accepted at the time of the hearing. The purpose of this requirement is to allow Board members adequate time to review the documents.

Members of the public who are disabled and require special accommodations or assistance at the meeting are required to notify Yvonne Sylva, Secretary, Board of Health, in writing at the Nevada State Health Division, 505 E. King Street, Room 201, Carson City, NV 89701, or by calling (702) 687-4740.

A copy of this notice and the proposed regulation amendments are on file for inspection at the following locations during normal business hours:

Bureau of Licensure and Certification, 1550 E. College Pkwy, Suite 158, Carson City, Nevada (702) 687-4475).

Bureau of Licensure and Certification, 4220 S. Maryland Parkway, Suite 810, Las Vegas, Nevada (702) 486-6515.

Bureau of Licensure and Certification, 1755 E. Plumb Lane, Suite 241, Reno, Nevada (702) 688-2888

Emergency Medical Services, 850 Elm Street, Elko, Nevada (702) 753-1154.

Emergency Medical Services, 100 Frankie, Tonopah, Nevada (702) 482-3722.

Copies may be obtained in person, by mail, or by calling (702) 687-4475. Copies are also available for review at all physical locations of program offices (see above) or the following main public libraries in each county:

- Carson City Library, 900 North Roop St.
  Carson City, NV 89701
- Churchill County Library, 533 S. Main St.
  Fallon, NV 89406
- Clark County Library, 4020 Maryland Parkway,
  Las Vegas, NV 89119
- Douglas County Library, 1625 Library Lane, (PO Box 337)
  Minden, NV 89423
- Elko County Library, 720 Court St.
  Elko, NV 89801
- Goldfield Public Library (Esmeralda Co.), Corner of Crook and Ramsey, (PO Box 430)
  Goldfield, NV 89013
- Eureka Branch Library, 10190 Monroe St.,
  Eureka, NV 89316
- Humboldt County Library, 85 East 5th St.,
  Winnemucca, NV 89445
- Battle Mountain Branch Library (Lander Co.), 6255 Broad St.,
  Battle Mountain, NV 89820
- Lincoln County Library, 63 Maine St., (PO Box 330)
  Pioche, NV 89043
- Lyon County Library, 20 Nevin Way,
  Yerington, NV 89447
- Mineral County Library, 125 A St., (PO Box 1390)
  Hawthorne, NV 89415
- Pershing County Library, 125 Central, (PO Box 781)
  Lovelock, NV 89419
- Storey County Library, 95 South R St., (PO Box 14)
  Virginia City, NV 89440
- Tonopah Public Library (Nye Co.), 171 Central, (PO Box 449)
  Tonopah, NV 89049
- Washoe County Library, 301 South Center St., (PO Box 2151)
  Reno, NV 89505
- White Pine County Library, 950 Campton St.,
  Ely, NV 89301

Per NRS 233B.064(2), upon adoption of any regulations, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

To be published in the Las Vegas Review-Journal, Reno Gazette-Journal and Elko Daily Free

Press on or before August 11, 1999.

Richard J. Panelli, Chief
July 27, 1999

PROPOSED REGULATION OF THE STATE BOARD OF HEALTH

POINT OF CARE TESTING

EXPLANATION – Italicized material is new; material in brackets [ ] is to be deleted

NOTE: Only those sections being changed are provided in this document.

Chapter 652 of NAC is hereby amended by adding thereto the provisions set fourth as sections 1 to 3, inclusive, of this regulations

Section 1

"Point of care testing" defined. Except as provided in NRS 652.217 and NRS 652.235, "Point of care testing" refers to clinical laboratory tests or examinations classified as waived or of moderate complexity pursuant to 42 CFR 493 Subpart A which are performed by a point of care testing device within a medical facility which is licensed pursuant to 449 of NRS and has a laboratory which is licensed pursuant to 652 of NRS.

Section 2

"Point of care testing device" defined; limitations on use.

1. ***"Point of care testing device" means a portable laboratory testing system which performs clinical laboratory tests or examinations classified as waived or of moderate complexity pursuant to 42 CFR 493 subpart A and includes analytical instruments, kits or procedures that are hand-carried or transported to the vicinity of the patient for immediate testing at the site of the patient.***
2. ***A point of care testing device may only be used if the device:***

   (a). Performs clinical laboratory tests or examinations on biological specimens that require no preparation after collection; and

(b). Provides clinical laboratory tests or examinations results directly from the instrument without calculation or discretionary intervention by the testing personnel during preanalytic and postanalytic phases.

3. *A point of care testing device may only be used under the following conditions:*

(a). In accordance with a patient test management system, a quality control program and comprehensive quality assurance program;

(b). In accordance with the instructions of the manufacturer of the device; and

(c). By properly qualified personnel under the supervision of a laboratory director.

4. *In order to use a point of care testing device, a person must be licensed or certified as a:*

(a). Director

(b). General Supervisor

(c). Clinical laboratory technologist

(d). Medical technician

(e). Blood-gas technologist

(f). Blood-gas technician

(g). Technologist

(h). Technician; or

(i). Point of care analyst

Section 3

Point of care analyst: Qualifications and activities.

1. *To qualify for a certificate as a point of care analyst, a person must provide verification from his laboratory director that he has successfully completed laboratory director*

approved education and training for preanalytical, postanalytical and analytical phases of the testing process, and;

2. Be one of the following medical professionals:

a. Registered nurse as described in NRS 632.019

b. Advanced practitioner of nursing as described in NRS 632.012

c. Licensed practical nurse as described in NRS 632.016

d. Practitioner of Respiratory care as described in NRS 640B

e. Physician assistant as described in NRS 630

f. Registered pharmacists participating as described in NRS 639.0124(8)

g. Certified laboratory assistant with a high school diploma or equivalent education and subsequent training under point-of-care testing program.

Section 4 NAC 652.455 is hereby amended to read as follows

652.455 Continuing education: Prerequisites to renewal of license or certificate.

1. Each director, general supervisor, technologist, technician, ~~[and]~~ pathologist's assistant ***and point of care testing analyst*** licensed or certified pursuant to this chapter shall complete 2 units of continuing education within the 2 years immediately preceding the application for renewal of his license or certificate. At least one-half of the unit must be from approved courses.

2. Each laboratory assistant or blood-gas assistant shall complete 1 unit of continuing education within the 2 years immediately preceding the application for renewal of his certificate.

MISCELLANEOUS PROVISIONS

Section 5 NAC 652.488 is hereby amended to read as follows

652.488 Fees. The following nonrefundable fees will be charged:

1. Licensure of laboratory

Initial:	
Annual test volume less than 25,000	$550
Annual test volume at least 25,000 but less than 100,000	800
Annual test volume 100,000 or more	1,150
Biennial renewal:	
Annual test volume less than 25,000	400
Annual test volume at least 25,000 but less than 100,000	600
Annual test volume 100,000 or more	800
Inspection conducted pursuant to NAC 652.320	300
Reinstatement:	
Annual test volume less than 25,000	550
Annual test volume at least 25,000 but less than 100,000	800
Annual test volume 100,000 or more	1,150

2. Licensure of director

Initial	$250
Biennial renewal	150
Reinstatement	250

3. Registration of laboratory operated pursuant to NRS 652.235 which is nonexempt pursuant to NAC 652.155

Initial	$300
Biennial renewal	200
Reinstatement	300

Inspection pursuant to NAC 652.320	100
4. Registration of laboratory operated pursuant to NRS 652.235 which is exempt pursuant to NAC 652.155	
Initial	$100
Biennial renewal	50
Inspection pursuant to NAC 652.320	100
5. Certification of personnel	
Initial:	
General supervisor	$150
Technologist	75
Technician	75
Point of care analyst	***40***
Laboratory, blood-gas or office laboratory assistant	30
Reinstatement:	
General supervisor	150
Technologist	75
Technician	50
Point of care analyst	***50***
Laboratory, blood-gas or office laboratory assistant	40
6. Placement of license or certificate in inactive status	$20
7. Issuance of original duplicate license or certificate	$20
8. Permit to operate laboratory at temporary location	$35
9. Change of location of laboratory	$160

10. Change of director of laboratory $160

11. Inspection for additional specialties and subspecialties in which tests will be performed at laboratory $160, plus $50 for each additional specialty or subspecialty

INFORMATIONAL STATEMENT PER NRS 233B.066

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.

Notice of public workshops held on October 16, 1998, in Las Vegas and October 19, 1998, in Reno was published in the Las Vegas Review Journal, Reno Gazette Journal, and Elko Daily Free Press on or before October 1, 1998. Notices of public workshops and proposed regulations were mailed to all county libraries in Nevada, laboratory directors, licensed laboratories, and interested parties.

Notice of public hearing regarding the Board's intent to adopt amendments was published in the Las Vegas Review Journal, Reno Gazette Journal, and Elko Daily Free Press on or before November 11, 1998. Notices of public hearing and proposed regulations were mailed to all county libraries in Nevada, laboratory directors, licensed laboratories, hospitals, and interested parties on November 5, 1998.

The Medical Laboratory Advisory Committee met on November 10, 1998, and unanimously recommended approval of the proposed point of care testing regulations. There was a lengthy discussion regarding exemption of the requirement for nurses to obtain a Point of Care Analysis certificate. The Bureau of Licensure and Certification and Deputy Attorney General Linda Anderson clarified this issue as being statutory rather than regulatory.

Notice of public workshops held on August 19, 1999, in Las Vegas was published in the Las Vegas Review Journal, Reno Gazette Journal, and Elko Daily Free Press on or before August 2, 1999. Notices of public workshops and proposed regulations were mailed to all county libraries in Nevada, laboratory directors, licensed laboratories, and interested parties.

Notice of public hearing regarding the Board's intent to adopt amendments was published in the Las Vegas Review Journal, Reno Gazette Journal, and Elko Daily Free Press on or before August 11, 1999. Notices of public hearing and proposed regulations were mailed to all county libraries in Nevada, laboratory directors, licensed laboratories, and interested parties on July 30, 1999.

In addition, copies of the proposed regulations were available during normal office hours at:

Bureau of Licensure and Certification - Carson City
Bureau of Licensure and Certification - Las Vegas
Bureau of Licensure and Certification - Reno
Nevada State Library
Emergency Medical Services - Elko
Emergency Medical Services – Tonopah

For public response copies of the minutes of the Board of Health meetings may be obtained by calling the Health Division at 684-4200.

2. THE NUMBER OF PERSONS WHO:

(A) ATTENDED THE HEARING;

Approximately 102 people attended the February 12, 1999, Board of Health hearing.
Approximately 37 people attended the September 10, 1999, Board of Health hearing.

(B) TESTIFIED AT EACH HEARING; AND

Eleven people testified at the February 12, 1999, Board of Health hearing.
No people testified at the September 10, 1999, Board of Health hearing.

(C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

Two people submitted written statements at the February 12, 1999, Board of Health 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 laboratory directors, licensed laboratories, hospitals and all interested parties the proposed regulations and notice for the workshops and Board of Health hearing. Public response was in the form of written statements and testimony at the workshops and 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.

Anticipated benefits to both laboratories regulated by NAC 652 and the public (the patients) will be an overall cost reduction as a result of decreased length of stay due to rapid return of results to

the physician. These benefits are both immediate and long term. There are no adverse effects

anticipated.

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

Establishing a certification fee issued for point of care testing analyst will fund the increased cost to the agency.

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.

NAC 652 and CLIA regulations (42 CFR Part 493 of the Code of Federal Regulations) have established requirements for the performance of laboratory testing, however, with the recent availability of small portable hand-held analyzers, bedside testing by healthcare professionals other than traditional laboratory technical staff required changes to existing 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 regulation provides a certification fee issued for point of care testing analyst. It will be up to the hospitals to decide how many nurses will need to apply for certification.