

**LCB File No. T012-98**

**TEMPORARY REGULATION OF THE STATE BOARD OF HEALTH**

**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, and 652. **The hearing is scheduled to begin at 9:00 a.m. on Friday, December 11, 1998, at the Washoe County District Health Department, Ninth and Wells Street, Reno, Nevada.**

**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.

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

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

**Amendments are to chapter 652 of NAC.**

**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.

**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 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 testing analyst, a person must successfully complete 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.

**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**

**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 non exempt 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
<u>Point of care analyst</u>	<u>50</u>
Laboratory, blood-gas, or office laboratory assistant	40
Biennial renewal:	
General supervisor	\$100
Technologist	50
Technician	50
<u>Point of care analyst</u>	<u>40</u>
Laboratory, blood-gas, or office laboratory assistant	30
Reinstatement:	
General supervisor	\$150
Technologist	75
Technician	75
<u>Point of care analyst</u>	<u>50</u>
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

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| 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.  |        |