

**ADOPTED REGULATION OF THE
STATE BOARD OF HEALTH**

LCB File No. R072-26

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

AUTHORITY: § 1, NRS 439.150, 439.200, 457.240, 652.100 and 652.125; § 2, NRS 439.200, 652.123, 652.130 and 652.260.

A REGULATION relating to medical laboratories; revising certain fees relating to the licensure and operation of a medical laboratory; revising the amount of certain monetary penalties imposed for certain violations; and providing other matters properly relating thereto.

Legislative Counsel’s Digest:

Under existing law, the State Board of Health is authorized to set reasonable fees for the licensing, registering, certifying, inspecting or granting of permits for any facility, establishment or service regulated by the Health Care Purchasing and Compliance Division of the Nevada Health Authority. (NRS 439.150) Existing law requires the operator of a medical laboratory to obtain a license from the Division. (NRS 652.035, 652.080) **Section 1** of this regulation revises the amount of certain fees that must be charged for: (1) the issuance, renewal and reinstatement of the licensure and registration of certain medical laboratories; (2) the certification of certain personnel; and (3) the performance of certain actions. (NAC 652.488)

Existing law authorizes the Division to impose an administrative penalty on a person or laboratory which violates chapter 652 of NRS and any regulations adopted pursuant thereto, the provisions of which govern the operation of medical laboratories in this State. Existing law additionally authorizes the Board to adopt regulations to carry out the provisions governing the imposition of such penalties. (NRS 652.260) **Section 2** of this regulation revises the amount of certain monetary penalties imposed by the Division. (NAC 652.550)

Section 1. NAC 652.488 is hereby amended to read as follows:

652.488 1. Except as otherwise provided in this section, the following fees will be charged:

- (a) Licensure of laboratory not described in paragraph (b), (c) or (d)

Initial:

Annual test volume less than 25,000.....	[\$1,100] \$1,177
Annual test volume at least 25,000 but less than 100,000.....	[3,000] 3,210
Annual test volume 100,000 or more	[4,000] 4,280

Biennial renewal:

Annual test volume less than 25,000.....	[800] 856
Annual test volume at least 25,000 but less than 100,000.....	[2,500] 2,675
Annual test volume 100,000 or more	[3,500] 3,745

Reinstatement:

Annual test volume less than 25,000.....	[1,100] 1,177
Annual test volume at least 25,000 but less than 100,000.....	[3,000] 3,210
Annual test volume 100,000 or more	[4,000] 4,280

(b) Licensure of laboratory operated by health district, district board of

health, county board of health or city or town board of health, or the State

Public Health Laboratory

Initial:

Annual test volume less than 25,000.....	[\$550] \$589
Annual test volume at least 25,000 but less than 100,000.....	[800] 856
Annual test volume 100,000 or more	[1,150] 1,230

Biennial renewal:

Annual test volume less than 25,000.....	[400] 428
Annual test volume at least 25,000 but less than 100,000.....	[600] 642
Annual test volume 100,000 or more	[800] 856

Reinstatement:

Annual test volume less than 25,000.....	[\$550]	<i>589</i>
Annual test volume at least 25,000 but less than 100,000.....	[\$800]	<i>856</i>
Annual test volume 100,000 or more	[\$1,150]	<i>1,231</i>

(c) Licensure of laboratory only for the collection of specimens

Initial	[\$500]	<i>\$535</i>
Biennial renewal.....	[\$300]	<i>321</i>
Reinstatement	[\$500]	<i>535</i>

(d) Licensure of HIV testing laboratory

Initial	[\$150]	<i>\$161</i>
Biennial renewal.....	[\$150]	<i>161</i>

(e) Licensure of director pursuant to paragraph (b) of subsection 3 of

NAC 652.175 or NAC 652.380 to 652.395, inclusive

Initial	[\$500]	<i>\$535</i>
Biennial renewal.....	[\$300]	<i>321</i>
Reinstatement	[\$500]	<i>535</i>

(f) Registration of laboratory operated pursuant to NRS 652.072 which

is nonexempt pursuant to NAC 652.155

Initial	[\$1,500]	<i>\$1,605</i>
Biennial renewal.....	[\$900]	<i>963</i>
Reinstatement	[\$1,500]	<i>1,605</i>

(g) Registration of laboratory operated pursuant to NRS 652.072

which is exempt pursuant to NAC 652.155

Initial	[\$500]	<i>\$535</i>
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Biennial renewal.....	[300] 321
(h) Certification of personnel	
Initial:	
General supervisor.....	[\$225] \$241
Technologist.....	[113] 121
Technician.....	[113] 121
Pathologist’s assistant.....	[113] 121
Point-of-care test analyst.....	[75] 80
Laboratory, blood-gas or office laboratory assistant.....	[60] 64
Biennial renewal:	
General supervisor.....	[150] 161
Technologist.....	[75] 80
Technician.....	[75] 80
Pathologist’s assistant.....	[75] 80
Point-of-care test analyst.....	[60] 64
Laboratory, blood-gas or office laboratory assistant.....	[45] 48
Reinstatement:	
General supervisor.....	[225] 241
Technologist.....	[113] 121
Technician.....	[113] 121
Pathologist’s assistant.....	[113] 121
Point-of-care test analyst.....	[75] 80
Laboratory, blood-gas or office laboratory assistant.....	[60] 64

(i) Placement of license or certificate in inactive status	[\$50] \$54
(j) Issuance of original duplicate license or certificate	[\$50] \$54
(k) Permit to operate laboratory at temporary location.....	[\$300] \$321
(l) Change of location of laboratory	[\$300] \$321
(m) Change of director of laboratory	[\$300] \$321
(n) Change of name of laboratory	[\$300] \$321
(o) Inspection following receipt of an application to perform additional tests at a laboratory (per application).....	[\$300] \$321
(p) Inspection of an outpatient center of a laboratory (per site)	
Initial inspection	[\$300] \$315
Inspection at time of biennial renewal	[\$150] 158

2. If the Division conducts an inspection of a laboratory that is located outside of this State, the Division shall assess the expenses that the Division incurs as a result of the inspection to the laboratory. The laboratory shall reimburse the Division for the expenses assessed pursuant to this subsection.

3. The Division shall not charge or collect a fee set forth in paragraph (l), (m) or (n) of subsection 1 to an HIV testing laboratory.

4. The holder of or an applicant for a license or certificate issued pursuant to chapter 652 of NRS, or an applicant for a permit to operate a laboratory at a temporary location issued pursuant to NAC 652.195, shall be deemed to have paid any fee otherwise required pursuant to subsection 1 if the holder or applicant:

(a) Is, or is employed by, a medical laboratory that is operated by a person, governmental entity or fire-fighting agency that holds a permit issued by a health authority pursuant to NRS 450B.200; and

(b) Has paid the fee for the permit established by a board pursuant to NRS 450B.200.

5. Upon the renewal of a license to operate a laboratory, other than an HIV testing laboratory, the licensee shall pay to the Division a fee equal to 6 percent of the biennial renewal fee set forth in subsection 1. The Division shall use the fees collected pursuant to this subsection during the immediately following fiscal year to support the system for the reporting of information on cancer and other neoplasms.

6. As used in this section:

(a) "Board" has the meaning ascribed to it in NRS 450B.060.

(b) "Health authority" has the meaning ascribed to it in NRS 450B.077.

(c) "Permit" has the meaning ascribed to it in NRS 450B.100.

Sec. 2. NAC 652.550 is hereby amended to read as follows:

652.550 1. In determining the amount of a monetary penalty, the Division:

(a) For a first violation with a severity level of four, shall impose a monetary penalty of ~~[\$1,000]~~ **\$1,070** per violation.

(b) For a first violation with a severity level of three, shall impose a monetary penalty of ~~[\$800]~~ **\$856** per violation.

(c) For a first violation with a severity level of two, may impose a monetary penalty of ~~[\$100]~~ **\$107** per violation. The Division may suspend this penalty if the laboratory corrects the violations within the time specified in the plan of correction submitted to the Division pursuant to NAC 652.320.

(d) For a second violation with a severity level of four discovered during any subsequent inspection, shall impose a monetary penalty of ~~[\$5,000]~~ \$5,350 per violation.

(e) For a second violation with a severity level of three discovered during any subsequent inspection, shall impose a monetary penalty of ~~[\$1,600]~~ \$1,712 per violation.

(f) For a second violation with a severity level of two discovered during any subsequent inspection, may impose a monetary penalty of ~~[\$200]~~ \$204 regardless of whether a penalty was imposed for the first violation.

(g) For a third or subsequent violation with a severity level of four discovered during any subsequent inspection, shall impose a monetary penalty of ~~[\$10,000]~~ \$10,700 per violation.

(h) For a third or subsequent violation with a severity level of three discovered during any subsequent inspection, shall impose a monetary penalty of ~~[\$3,200]~~ \$3,424 per violation.

(i) For a third or subsequent violation with a severity level of two discovered during any subsequent inspection, may impose a monetary penalty of ~~[\$400]~~ \$428 per violation regardless of whether a first or second monetary penalty was imposed.

2. The Division shall not impose a monetary penalty for a violation with a severity level of one.

3. If the same violation that was discovered during the initial inspection is found during a subsequent inspection conducted to evaluate compliance with a plan of correction submitted to the Division pursuant to subsection 5 of NAC 652.320, there is a rebuttable presumption that the violation continued through the period between the inspection and the subsequent inspection. The Division may impose an additional monetary penalty for such a violation only if the subsequent inspection is made and the violation is found to be present after the laboratory has been notified of the violation and given an opportunity to correct the violation.

4. A laboratory may, upon approval by the Division, use a monetary penalty that would otherwise be imposed by the Division to correct the violation and to put measures in place to prevent the violation from reoccurring. In such a case, the laboratory must provide proof to the Division that the money was used to correct the violation. If the amount of the monetary penalty is greater than the cost to correct the violation, the laboratory must pay to the Division the portion of the monetary penalty that was not used to correct the violation.