

Amendment No. 7

Senate Amendment to Senate Bill No. 40 (BDR 54-314)

Proposed by: Senate Committee on Commerce, Labor and Energy**Amends:** Summary: No Title: No Preamble: No Joint Sponsorship: No Digest: No

Adoption of this amendment will MAINTAIN the 2/3s majority vote requirement for final passage of S.B. 40 (§ 6).

ASSEMBLY ACTION				Initial and Date	SENATE ACTION				Initial and Date
Adopted	<input type="checkbox"/>	Lost	<input type="checkbox"/>	_____	Adopted	<input type="checkbox"/>	Lost	<input type="checkbox"/>	_____
Concurred In	<input type="checkbox"/>	Not	<input type="checkbox"/>	_____	Concurred In	<input type="checkbox"/>	Not	<input type="checkbox"/>	_____
Receded	<input type="checkbox"/>	Not	<input type="checkbox"/>	_____	Receded	<input type="checkbox"/>	Not	<input type="checkbox"/>	_____

EXPLANATION: Matter in (1) *blue bold italics* is new language in the original bill; (2) *green bold italic underlining* is new language proposed in this amendment; (3) ~~red strikethrough~~ is deleted language in the original bill; (4) ~~purple double strikethrough~~ is language proposed to be deleted in this amendment; (5) orange double underlining is deleted language in the original bill that is proposed to be retained in this amendment; and (6) *green bold underlining* is newly added transitory language.

KRO/HAC



Date: 3/29/2013

S.B. No. 40—Revises provisions relating to medical laboratories. (BDR 54-314)



SENATE BILL NO. 40—COMMITTEE ON
COMMERCE, LABOR, AND ENERGY

(ON BEHALF OF THE HEALTH DIVISION)

PREFILED DECEMBER 20, 2012

Referred to Committee on Commerce, Labor, and Energy

SUMMARY—Revises provisions relating to medical laboratories. (BDR 54-314)

FISCAL NOTE: Effect on Local Government: No.
Effect on the State: Yes.

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

AN ACT relating to medical laboratories; revising provisions governing the application for the licensing of a medical laboratory; revising the requirements to qualify for certification as an assistant in a medical laboratory; increasing the maximum amount of administrative penalties that may be imposed for violations of provisions governing medical laboratories; making various other changes relating to medical laboratories; requiring the State Board of Health to adopt certain regulations; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Under existing law, an application for the licensing of a medical laboratory is required to be made under oath on a form prescribed by the Health Division of the Department of Health and Human Services and must contain certain other information. (NRS 652.090) **Section 1** of this bill eliminates the requirement that applications for the licensing of a medical laboratory be made under oath and adds the requirement that these applications include the proof of identity of the laboratory director.

Under existing law, to qualify for certification as an assistant in a medical laboratory, a person is required to be a high school graduate or have a general equivalency diploma and is required to either complete 6 months of approved training and demonstrate an ability to perform laboratory procedures or complete a course of instruction that qualifies him or her to take and pass an examination for certification in phlebotomy. (NRS 652.127) **Section 3** of this bill instead requires that, to qualify for certification as an assistant in a medical laboratory, a person must meet the qualifications established by regulations adopted by the State Board of Health.

Existing law authorizes certain licensed medical professionals to perform any laboratory test which is classified as a waived test pursuant to Subpart A of Part 493 of Title 42 of the Code of Federal Regulations. **Sections 4 and 5** of this bill clarify that those licensed medical professionals may perform such waived tests without obtaining certification as an assistant in a medical laboratory.

Under existing law, any person or laboratory violating any of the provisions governing medical laboratories is required to pay a fine ranging from \$250 to \$500 for each violation. (NRS 652.260) **Section 6** of this bill authorizes the Health Division to impose an

administrative penalty not to exceed \$10,000 for each violation and provides criteria for determining the amount of the administrative penalty to be imposed for a violation. **Section 6** also authorizes the Health Division to require any person or medical laboratory that violates the provisions governing medical laboratories to take any action necessary to correct the violation.

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN
SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. NRS 652.090 is hereby amended to read as follows:

652.090 **1.** An application for a license must be ~~made under oath~~ on a form prescribed by the Health Division and must contain the following information:

~~1.1~~ **(a)** The name and location of the laboratory;

~~1.2~~ **(b)** The name *and proof of identity* of the laboratory director;

~~1.3~~ **(c)** The name of the owner or owners of the laboratory or, if a corporation, the names of the officers, directors and beneficial owners of 10 percent or more of its shares;

~~1.4~~ **(d)** A description of the program and services provided by the laboratory; and

~~1.5~~ **(e)** Such other information as the Health Division may deem necessary or expedient to carry out its powers and duties under this chapter.

2. The Board shall adopt regulations to carry out the provisions of subsection 1, including, without limitation, regulations setting forth the acceptable forms of proof of identity that a laboratory director must include in an application pursuant to paragraph (b) of subsection 1.

Sec. 2. NRS 652.123 is hereby amended to read as follows:

652.123 Regulations adopted by the Board pursuant to this chapter may not be more stringent than the provisions of Part 493 of Title 42 of the Code of Federal Regulations, except that the Board may adopt regulations which are more stringent relating to:

1. Any laboratory test, other than a test for the detection of the human immunodeficiency virus, classified as a waived test pursuant to the provisions of Part 493 of Title 42 of the Code of Federal Regulations; ~~and~~

2. The qualifications and duties of the personnel of a medical laboratory ~~;~~ **and**

3. The administrative penalties that may be imposed for violating any of the provisions of this chapter or regulations adopted pursuant thereto.

Sec. 3. NRS 652.127 is hereby amended to read as follows:

652.127 **1.** To qualify for certification as an assistant in a medical laboratory, a person must ~~be a high school graduate or have a general equivalency diploma and:~~

~~— 1. Must complete at least 6 months of training approved by the Board and demonstrate an ability to perform laboratory procedures in the medical laboratory where he or she receives the training; or~~

~~— 2. Must:~~

~~— (a) Complete a course of instruction that qualifies him or her to take an examination for certification in phlebotomy that is administered by:~~

~~— (1) The American Medical Technologists;~~

~~— (2) The American Society of Clinical Pathologists; or~~

~~— (3) The National Certification Agency; and~~

~~— (b) Pass an examination specified in paragraph (a).]~~ **meet the qualifications established by the Board by regulation.**

1 **2. The Board shall adopt such regulations as necessary to carry out the**
2 **provisions of this section.**

3 **Sec. 4.** NRS 652.210 is hereby amended to read as follows:

4 652.210 1. Except as otherwise provided in subsection 2 and NRS 126.121,
5 no person other than a licensed physician, a licensed optometrist, a licensed
6 practical nurse, a registered nurse, a perfusionist, a physician assistant licensed
7 pursuant to chapter 630 or 633 of NRS, a certified intermediate emergency medical
8 technician, a certified advanced emergency medical technician, a practitioner of
9 respiratory care licensed pursuant to chapter 630 of NRS or a licensed dentist may
10 manipulate a person for the collection of specimens. ***The persons described in this***
11 ***subsection may perform any laboratory test which is classified as a waived test***
12 ***pursuant to Subpart A of Part 493 of Title 42 of the Code of Federal Regulations***
13 ***without obtaining certification as an assistant in a medical laboratory pursuant to***
14 ***NRS 652.127.***

15 2. The technical personnel of a laboratory may collect blood, remove stomach
16 contents, perform certain diagnostic skin tests or field blood tests or collect material
17 for smears and cultures.

18 **Sec. 5.** NRS 652.217 is hereby amended to read as follows:

19 652.217 1. A licensed nurse who is employed by a medical facility which is
20 licensed pursuant to chapter 449 of NRS may perform any laboratory test which is
21 classified as a waived test pursuant to Subpart A of Part 493 of Title 42 of the Code
22 of Federal Regulations if the laboratory director or a person designated by the
23 laboratory director:

24 (a) Verifies that the nurse is competent to perform the test;

25 (b) Ensures that the test is performed in accordance with any manufacturer's
26 instructions; and

27 (c) Validates and verifies the manner in which the test is performed through the
28 use of controls which ensure accurate and reliable results of the test.

29 ***2. A licensed nurse described in subsection 1 may perform any laboratory***
30 ***test which is classified a waived test pursuant to Subpart A of Part 493 of Title 42***
31 ***of the Code of Federal Regulations without obtaining certification as an assistant***
32 ***in a medical laboratory pursuant to NRS 652.127.***

33 **3.** Licensed or certified personnel of a laboratory licensed pursuant to this
34 chapter may perform any laboratory test which is classified as a waived test
35 pursuant to Subpart A of Part 493 of Title 42 of the Code of Federal Regulations on
36 the premises of an outpatient center of the laboratory or at a patient's residence if
37 the laboratory director or a person designated by the laboratory director:

38 (a) Verifies that the person is competent to perform the test;

39 (b) Ensures that the test is performed in accordance with any manufacturer's
40 instructions;

41 (c) Validates and verifies the manner in which the test is performed through the
42 use of controls which ensure accurate and reliable results of the test; and

43 (d) Ensures compliance with any requirements for safety adopted by the Board.

44 **Sec. 6.** NRS 652.260 is hereby amended to read as follows:

45 652.260 ~~{Any}~~

46 **1. If a** person or laboratory ~~{violating}~~ **violates** any of the provisions of this
47 chapter ~~{shall be punished by a fine}~~ **or the regulations adopted pursuant thereto,**
48 **the Health Division may, after giving notice and opportunity to be heard:**

49 ***(a) Impose an administrative penalty*** of not more than ~~{ \$250 for the first~~
50 ~~offense and not more than \$500 for any subsequent offense.}~~ ***\$10,000; and***

51 ***(b) Require the person or laboratory to take any action necessary to correct***
52 ***the violation.***

2. Each act in violation of this chapter *or the regulations adopted pursuant thereto* constitutes a separate offense.

3. *In determining the amount of an administrative penalty to be imposed pursuant to this section, the Health Division shall consider:*

(a) *The severity of the violation, including, without limitation:*

(1) *The probability that death or serious harm to the health or safety of a person may occur as a result of the violation;*

(2) *The severity of the potential or actual harm that may occur to any person as a result of the violation; and*

(3) *The extent to which the provisions of this chapter or the regulations adopted pursuant thereto were violated;*

(b) *Whether the person or laboratory has previously violated the provisions of this chapter or the regulations adopted pursuant thereto; and*

(c) *Any other facts or circumstances that the Health Division determines are relevant.*

4. *If the person or laboratory fails to pay the administrative penalty imposed pursuant to this section after the time for an appeal has expired, the Health Division may:*

(a) *Suspend the license of the person or laboratory;*

(b) *Impose interest on the unpaid administrative penalty at a rate of 10 percent from the date on which the time for an appeal expired until the date the administrative penalty is paid; and*

(c) *Collect court costs, reasonable attorney's fees, the costs of an investigation and other costs incurred to collect the administrative penalty.*

5. *Except as otherwise provided in this section, all money collected from administrative penalties imposed pursuant to this section must be deposited in the State General Fund.*

6. *The money collected from such administrative penalties may be accounted for separately and used by the Health Division to administer and carry out the provisions of this chapter and to protect the health, safety and well-being of patients in accordance with applicable state and federal standards if:*

(a) *The person or laboratory pays the administrative penalty without exercising the right to a hearing to contest the penalty; or*

(b) *The administrative penalty is imposed in a hearing conducted by a hearing officer or panel appointed by the Health Division.*

7. *The Health Division may appoint one or more hearing officers or panels and may delegate to those hearing officers or panels the power of the Health Division to conduct hearings, determine violations and impose the administrative penalties authorized by this section.*

8. *If money collected from an administrative penalty is deposited in the State General Fund, the Health Division may present a claim to the State Board of Examiners for recommendation to the Interim Finance Committee if money is needed to pay court costs, attorney's fees, the costs of an investigation or other costs incurred to collect the administrative penalty.*

9. *The Board may adopt regulations to carry out the provisions of this section.*

Sec. 7. NRS 484C.250 is hereby amended to read as follows:

484C.250 1. The results of any blood test administered under the provisions of NRS 484C.160 or 484C.180 are not admissible in any hearing or criminal action arising out of acts alleged to have been committed by a person who was driving or in actual physical control of a vehicle while under the influence of intoxicating liquor or a controlled substance or who was engaging in any other conduct prohibited by NRS 484C.110, 484C.120, 484C.130 or 484C.430 unless:

(a) The blood tested was withdrawn by a person, other than an arresting officer, who:

(1) Is a physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, registered nurse, licensed practical nurse, emergency medical technician or a phlebotomist, technician, technologist or assistant employed in a medical laboratory; or

(2) Has special knowledge, skill, experience, training and education in withdrawing blood in a medically acceptable manner, including, without limitation, a person qualified as an expert on that subject in a court of competent jurisdiction or a person who has completed a course of instruction ~~described in subsection 2 of NRS 652.127;~~ *that qualifies him or her to take an examination in phlebotomy that is administered by the American Medical Technologists ~~or~~ or the American Society ~~for~~ for Clinical ~~Pathologists or the National Certification Agency for Medical Laboratory Personnel;~~ Pathology;* and

(b) The test was performed on whole blood, except if the sample was clotted when it was received by the laboratory, the test may be performed on blood serum or plasma.

2. The limitation contained in paragraph (a) of subsection 1 does not apply to the taking of a chemical test of the urine, breath or other bodily substance.

3. No person listed in paragraph (a) of subsection 1 incurs any civil or criminal liability as a result of the administering of a blood test when requested by a police officer or the person to be tested to administer the test.

Sec. 8. NRS 488.500 is hereby amended to read as follows:

488.500 1. The results of any blood test administered under the provisions of NRS 488.460 or 488.490 are not admissible in any criminal action arising out of acts alleged to have been committed by a person who was operating or in actual physical control of a vessel under power or sail while under the influence of intoxicating liquor or a controlled substance or who was engaging in any other conduct prohibited by NRS 488.410, 488.420 or 488.425 unless:

(a) The blood tested was withdrawn by a person, other than an arresting officer, who:

(1) Is a physician, registered nurse, licensed practical nurse, emergency medical technician or a phlebotomist, technician, technologist or assistant employed in a medical laboratory; or

(2) Has special knowledge, skill, experience, training and education in withdrawing blood in a medically acceptable manner, including, without limitation, a person qualified as an expert on that subject in a court of competent jurisdiction or a person who has completed a course of instruction ~~described in subsection 2 of NRS 652.127;~~ *that qualifies him or her to take an examination in phlebotomy that is administered by the American Medical Technologists ~~or~~ or the American Society ~~for~~ for Clinical ~~Pathologists or the National Certification Agency for Medical Laboratory Personnel;~~ Pathology;* and

(b) The test was performed on whole blood, except if the sample was clotted when it was received by the laboratory, the test may be performed on blood serum or plasma.

2. The limitation contained in paragraph (a) of subsection 1 does not apply to the taking of a chemical test of the urine, breath or other bodily substance.

3. No person listed in paragraph (a) of subsection 1 incurs any civil or criminal liability as a result of the administering of a blood test when requested by a peace officer or the person to be tested to administer the test.

Sec. 9. The amendatory provisions of section 3 of this act do not apply to a person who has obtained certification as an assistant in a medical laboratory before January 1, 2014.

1 **Sec. 10.** This act becomes effective:

2 1. Upon passage and approval for the purposes of adopting regulations and
3 performing any other preparatory administrative tasks that are necessary to carry
4 out the provisions of this act; and

5 2. On January 1, 2014, for all other purposes.