REQUIRES TWO-THIRDS MAJORITY VOTE (§ 6) (Reprinted with amendments adopted on April 4, 2013) S.B. 40 FIRST REPRINT

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.

EXPLANATION - Matter in *bolded italics* is new; matter between brackets for its 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 1 23456789 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 10 11 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 12 13 certification in phlebotomy. (NRS 652.127) Section 3 of this bill instead requires 14 that, to qualify for certification as an assistant in a medical laboratory, a person





15 must meet the qualifications established by regulations adopted by the State Board 16 of Health.

17 Existing law authorizes certain licensed medical professionals to perform any 18 laboratory test which is classified as a waived test pursuant to Subpart A of Part 19 493 of Title 42 of the Code of Federal Regulations. **Sections 4 and 5** of this bill 20 clarify that those licensed medical professionals may perform such waived tests 21 without obtaining certification as an assistant in a medical laboratory.

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

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 *I*. 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.] (a) The name and location of the laboratory;

6 [2.] (b) The name and proof of identity of the laboratory 7 director;

8 [3.] (c) The name of the owner or owners of the laboratory or, if 9 a corporation, the names of the officers, directors and beneficial 10 owners of 10 percent or more of its shares;

11 [4.] (*d*) A description of the program and services provided by 12 the laboratory; and

13 [5.] (e) Such other information as the Health Division may 14 deem necessary or expedient to carry out its powers and duties 15 under this chapter.

16 2. The Board shall adopt regulations to carry out the 17 provisions of subsection 1, including, without limitation, 18 regulations setting forth the acceptable forms of proof of identity 19 that a laboratory director must include in an application pursuant 20 to paragraph (b) of subsection 1.

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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





1 to the provisions of Part 493 of Title 42 of the Code of Federal 2 Regulations; fand The qualifications and duties of the personnel of a medical 3 2. 4 laboratory [.]; and 3. The administrative penalties that may be imposed for 5 violating any of the provisions of this chapter or regulations 6 7 adopted pursuant thereto. 8 **Sec. 3.** NRS 652.127 is hereby amended to read as follows: 9 652.127 **1**. To qualify for certification as an assistant in a 10 medical laboratory, a person must [be a high school graduate or 11 have a general equivalency diploma and: 12 1. Must complete at least 6 months of training approved by the 13 Board and demonstrate an ability to perform laboratory procedures in the medical laboratory where he or she receives the training; or-14 15 -2. Must: 16 (a) Complete a course of instruction that qualifies him or her to 17 take an examination for certification in phlebotomy that is 18 administered by: (1) The American Medical Technologists; 19 20 (2) The American Society of Clinical Pathologists; or (3) The National Certification Agency; and 21 22 (b) Pass an examination specified in paragraph (a).] meet the 23 qualifications established by the Board by regulation. The Board shall adopt such regulations as necessary to 24 2. 25 carry out the provisions of this section. 26 **Sec. 4.** NRS 652.210 is hereby amended to read as follows: 652.210 1. Except as otherwise provided in subsection 2 and 27 28 NRS 126.121, no person other than a licensed physician, a licensed 29 optometrist, a licensed practical nurse, a registered nurse, a 30 perfusionist, a physician assistant licensed pursuant to chapter 630 31 or 633 of NRS, a certified intermediate emergency medical technician, a certified advanced emergency medical technician, a 32 33 practitioner of respiratory care licensed pursuant to chapter 630 of NRS or a licensed dentist may manipulate a person for the collection 34 of specimens. The persons described in this subsection may 35 perform any laboratory test which is classified as a waived test 36 pursuant to Subpart A of Part 493 of Title 42 of the Code of 37 38 Federal Regulations without obtaining certification as an assistant in a medical laboratory pursuant to NRS 652.127. 39 40 2. The technical personnel of a laboratory may collect blood, 41 remove stomach contents, perform certain diagnostic skin tests or field blood tests or collect material for smears and cultures. 42 43 **Sec. 5.** NRS 652.217 is hereby amended to read as follows: 44 652.217 1. A licensed nurse who is employed by a medical 45 facility which is licensed pursuant to chapter 449 of NRS may





1 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 2 Regulations if the laboratory director or a person designated by the 3 4 laboratory director:

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

6 (b) Ensures that the test is performed in accordance with any 7 manufacturer's instructions; and

8 (c) Validates and verifies the manner in which the test is 9 performed through the use of controls which ensure accurate and 10 reliable results of the test.

11 2. A licensed nurse described in subsection 1 may perform 12 any laboratory test which is classified a waived test pursuant to 13 Subpart A of Part 493 of Title 42 of the Code of Federal 14 Regulations without obtaining certification as an assistant in a 15 medical laboratory pursuant to NRS 652.127.

16 3. Licensed or certified personnel of a laboratory licensed 17 pursuant to this chapter may perform any laboratory test which is 18 classified as a waived test pursuant to Subpart A of Part 493 of Title 42 of the Code of Federal Regulations on the premises of an 19 outpatient center of the laboratory or at a patient's residence if the 20 laboratory director or a person designated by the laboratory director: 21 22

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

23 (b) Ensures that the test is performed in accordance with any 24 manufacturer's instructions:

25 (c) Validates and verifies the manner in which the test is 26 performed through the use of controls which ensure accurate and 27 reliable results of the test: and

28 (d) Ensures compliance with any requirements for safety 29 adopted by the Board.

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

31 652.260 [Any]

1. If a person or laboratory [violating] violates any of the 32 provisions of this chapter [shall be punished by a fine] or the 33 regulations adopted pursuant thereto, the Health Division may, 34 35 after giving notice and opportunity to be heard:

36 (a) Impose an administrative penalty of not more than [\$250] 37 for the first offense and not more than \$500 for any subsequent 38 offense.] \$10,000; and

(b) Require the person or laboratory to take any action 39 necessary to correct the violation. 40

41 2. Each act in violation of this chapter or the regulations 42 *adopted pursuant thereto* constitutes a separate offense.

43 *În determining the amount of an administrative penalty to* 3. 44 be imposed pursuant to this section, the Health Division shall 45 consider:





1 (a) The severity of the violation, including, without limitation: 2 (1) The probability that death or serious harm to the health or safety of a person may occur as a result of the violation; 3 (2) The severity of the potential or actual harm that may 4 occur to any person as a result of the violation; and 5 (3) The extent to which the provisions of this chapter or the 6 regulations adopted pursuant thereto were violated; 7 (b) Whether the person or laboratory has previously violated 8 the provisions of this chapter or the regulations adopted pursuant 9 10 thereto; and (c) Any other facts or circumstances that the Health Division 11 12 determines are relevant. 13 4. If the person or laboratory fails to pay the administrative 14 penalty imposed pursuant to this section after the time for an 15 appeal has expired, the Health Division may: 16 (a) Suspend the license of the person or laboratory; (b) Impose interest on the unpaid administrative penalty at a 17 rate of 10 percent from the date on which the time for an appeal 18 expired until the date the administrative penalty is paid; and 19 (c) Collect court costs, reasonable attorney's fees, the costs of 20 an investigation and other costs incurred to collect the 21 22 administrative penalty. 5. Except as otherwise provided in this section, all money 23 collected from administrative penalties imposed pursuant to this 24 25 section must be deposited in the State General Fund. 6. The money collected from such administrative penalties 26 27 may be accounted for separately and used by the Health Division to administer and carry out the provisions of this chapter and to 28 29 protect the health, safety and well-being of patients in accordance with applicable state and federal standards if: 30 31 (a) The person or laboratory pays the administrative penalty 32 without exercising the right to a hearing to contest the penalty; or (b) The administrative penalty is imposed in a hearing 33 conducted by a hearing officer or panel appointed by the Health 34 35 Division. 7. The Health Division may appoint one or more hearing 36 officers or panels and may delegate to those hearing officers or 37 panels the power of the Health Division to conduct hearings, 38 determine violations and impose the administrative penalties 39 authorized by this section. 40 8. If money collected from an administrative penalty is 41 deposited in the State General Fund, the Health Division may 42 present a claim to the State Board of Examiners for 43 44 recommendation to the Interim Finance Committee if money is 45 needed to pay court costs, attorney's fees, the costs of an





1 investigation or other costs incurred to collect the administrative 2 penalty.

3 The Board may adopt regulations to carry out the 9. 4 provisions of this section.

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

6 484C.250 1. The results of any blood test administered under 7 the provisions of NRS 484C.160 or 484C.180 are not admissible in 8 any hearing or criminal action arising out of acts alleged to have 9 been committed by a person who was driving or in actual physical 10 control of a vehicle while under the influence of intoxicating liquor 11 or a controlled substance or who was engaging in any other conduct prohibited by NRS 484C.110, 484C.120, 484C.130 or 484C.430 12 13 unless:

14 (a) The blood tested was withdrawn by a person, other than an 15 arresting officer, who:

16 (1) Is a physician, physician assistant licensed pursuant to 17 chapter 630 or 633 of NRS, registered nurse, licensed practical 18 nurse, emergency medical technician or a phlebotomist, technician, 19 technologist or assistant employed in a medical laboratory; or

(2) Has special knowledge, skill, experience, training and 20 education in withdrawing blood in a medically acceptable manner, 21 22 including, without limitation, a person qualified as an expert on that 23 subject in a court of competent jurisdiction or a person who has 24 completed a course of instruction [described in subsection 2 of NRS] 25 652.127;] that qualifies him or her to take an examination in phlebotomy that is administered by the American Medical 26 27 Technologists or the American Society for Clinical Pathology; and

28 (b) The test was performed on whole blood, except if the sample 29 was clotted when it was received by the laboratory, the test may be 30 performed on blood serum or plasma.

31 2. The limitation contained in paragraph (a) of subsection 1 32 does not apply to the taking of a chemical test of the urine, breath or 33 other bodily substance.

34 No person listed in paragraph (a) of subsection 1 incurs any 3. 35 civil or criminal liability as a result of the administering of a blood 36 test when requested by a police officer or the person to be tested to 37 administer the test. 38

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

39 488.500 1. The results of any blood test administered under the provisions of NRS 488.460 or 488.490 are not admissible in any 40 41 criminal action arising out of acts alleged to have been committed by a person who was operating or in actual physical control of a 42 vessel under power or sail while under the influence of intoxicating 43 44 liquor or a controlled substance or who was engaging in any other 45 conduct prohibited by NRS 488.410, 488.420 or 488.425 unless:





1 (a) The blood tested was withdrawn by a person, other than an 2 arresting officer, who:

3 (1) Is a physician, registered nurse, licensed practical nurse, 4 emergency medical technician or a phlebotomist, technician, 5 technologist or assistant employed in a medical laboratory; or

(2) Has special knowledge, skill, experience, training and 6 7 education in withdrawing blood in a medically acceptable manner, 8 including, without limitation, a person gualified as an expert on that 9 subject in a court of competent jurisdiction or a person who has 10 completed a course of instruction described in subsection 2 of NRS 652.127;] that qualifies him or her to take an examination in 11 phlebotomy that is administered by the American Medical 12 13 Technologists or the American Society for Clinical 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.

17 2. The limitation contained in paragraph (a) of subsection 1 18 does not apply to the taking of a chemical test of the urine, breath or 19 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.

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Sec. 10. This act becomes effective:

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

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



