

Amendment No. CA5

Conference Committee Amendment to Senate Bill No. 283 Second Reprint	(BDR 54-555)
Proposed by: Conference Committee	
Amends: Summary: Yes Title: Yes Preamble: No Joint Sponsorship: No Digest: Yes	

Adoption of this amendment will MAINTAIN the unfunded mandate not requested by the affected local government to S.B. 283 R2 (§ 1).
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EXPLANATION: Matter in (1) *blue bold italics* is new language in the original bill; (2) variations of green bold underlining is language proposed to be added 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 proposed to be retained in this amendment.



SENATE BILL NO. 283—SENATORS PAZINA, DONATE; DALY, DONDERO LOOP, FLORES,
D. HARRIS, LANGE, NEAL, NGUYEN, OHRENSCHALL AND SCHEIBLE

MARCH 15, 2023

Referred to Committee on Commerce and Labor

SUMMARY—Revises certain provisions relating to health care ~~. [records.]~~
(BDR 54-555)

FISCAL NOTE: Effect on Local Government: May have Fiscal Impact.
Effect on the State: Yes.

CONTAINS UNFUNDED MANDATE (§ 1)
(NOT REQUESTED BY AFFECTED LOCAL GOVERNMENT)

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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 health care; requiring a custodian of health care records to furnish health care records electronically under certain circumstances; prohibiting a custodian of health care records from charging a fee that exceeds a certain amount to furnish health care records electronically if the health care records are maintained electronically; authorizing a person to disclose the genetic information of another person in accordance with certain federal law; revising the circumstances under which a physician is authorized to prescribe or recommend and a manufacturer is authorized to provide or make available an investigational drug, biological product or device; authorizing a physician to prescribe or recommend an individualized investigational treatment under certain circumstances; requiring the reporting of certain information concerning individualized investigational treatments and investigational drugs, biological products and devices to certain governmental entities; revising the method by which a collection agency must notify a medical debtor before taking any action to collect a medical debt; authorizing a manufacturer to provide or make available an individualized investigational treatment to a patient under certain circumstances; authorizing the imposition of administrative penalties for certain violations; prohibiting an officer, employee or agent of this State from preventing or attempting to prevent a patient from accessing an individualized investigational treatment; requiring an insurer, third-party administrator or employer to furnish health care records in certain circumstances; prescribing the maximum amount of any fee

charged to furnish health care records in those circumstances; providing a penalty; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires each custodian of health care records to make health care records available for inspection by a patient, certain representatives of a patient and certain government officials. (NRS 629.061) Upon request of such a person, **section 1** of this bill requires a custodian of health care records to electronically transmit the health care records to the person or, if the patient has provided written authorization for records to be furnished to another person or entity, to that person or entity.

Existing law authorizes a custodian of health care records to charge certain fees for furnishing a copy of health care records. (NRS 629.061) **Section 1:** (1) generally prohibits a custodian of health care records from charging a fee that exceeds \$40 or other amounts prescribed by existing law for furnishing a copy of health care records electronically if the custodian of health care records maintains such health care records electronically; and (2) authorizes a custodian of health care records, other than the health care records of a state or local governmental entity, to charge certain additional fees in certain circumstances. **Section 2** of this bill makes a conforming change to indicate the proper placement of **section 1** in the Nevada Revised Statutes.

Existing law prohibits a person from disclosing or compelling a person to disclose the identity of a person who was the subject of a genetic test or any genetic information of another person, with certain exceptions, without first obtaining the informed consent of that person or his or her legal guardian. (NRS 629.171) **Section 1.5** of this bill adds an exception to this prohibition to authorize a person to disclose such information as permitted by the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.

Existing federal law prohibits the introduction of a drug or biological product into interstate commerce if the drug or biological product has not received approval from the United States Food and Drug Administration. (21 U.S.C. § 355; 42 U.S.C. § 262) Existing federal regulations allow expanded access to investigational drugs and biological products for patients who have a life-threatening or severely debilitating disease or condition, or a serious or immediately life-threatening illness, under certain circumstances. (21 C.F.R. Part 312, Subparts E and I) Existing Nevada law authorizes the manufacturer of an investigational drug, biological product or device, upon the prescription or recommendation of a physician, to provide or make available the investigational drug, biological product or device to a patient who has been diagnosed with a terminal condition that will, without the administration of life-sustaining treatment, result in death within 1 year. (NRS 454.690) Existing law authorizes a physician to issue a prescription or recommendation for an investigational drug, biological product or device if the physician has: (1) diagnosed the patient with a terminal condition; (2) consulted with the patient and the patient and physician have determined that no treatment currently approved by the United States Food and Drug Administration is adequate to treat the terminal condition; and (3) obtained informed, written consent to the use of the investigational drug, biological product or device from the patient or his or her representative, parent or guardian. (NRS 630.3735, 633.6945) Sections 1.6, 1.9 and 2.7 of this bill: (1) remove the requirement that a patient be diagnosed with a terminal condition before a physician is authorized to prescribe or recommend, and a manufacturer is authorized to provide, an investigational drug, biological product or device; and (2) instead require the patient to be diagnosed with a life-threatening or severely debilitating disease or condition before such actions are authorized. Section 2.7 additionally: (1) authorizes the manufacturer of an individualized investigational treatment to make the treatment available to such a patient under similar conditions to an investigational drug, biological product or device if the manufacturer operates in a facility that meets certain federal requirements for the protection of human subjects; and (2) defines "individualized investigational treatment" to mean a drug, biological product or device that is unique to and produced exclusively for use by an individual patient based on the genetic profile of the patient. Sections 1.6

53 and 1.9 authorize a physician to prescribe or recommend an individualized
54 investigational treatment under similar conditions to those under which a physician is
55 authorized to recommend an investigational drug, biological product or device, except
56 that sections 1.6 and 1.9 require the physician to additionally conduct certain
57 biochemical analyses.

58 Section 2.7 requires a manufacturer that provides or makes available an
59 individualized investigational treatment or investigational drug, biological product or
60 device to establish a hotline for patients who develop adverse effects or symptoms.
61 Section 2.7 also requires such a manufacturer to submit quarterly reports to the Board
62 of Medical Examiners and the State Board of Osteopathic Medicine summarizing the
63 individualized investigational treatments or investigational drugs, biological products or
64 devices provided to patients of physicians who are licensed by those boards. Section 2.7
65 establishes an administrative penalty to be imposed against a manufacturer that fails to
66 submit the required report. Section 2.7 also provides that if a patient dies while being
67 treated with an individualized investigational treatment or investigational drug,
68 biological product or device, the heir or heirs of the deceased patient are not personally
69 liable for any outstanding debt related to such treatment.

70 Existing law makes it a misdemeanor for any officer, employee or agent of this State
71 to prevent or attempt to prevent a patient from accessing an investigational drug,
72 biological product or device if certain requirements are met. (NRS 454.690) Section 2.7
73 additionally: (1) provides that counseling, advice or a recommendation from a physician
74 consistent with medical standards of care is not a violation; and (2) makes it a
75 misdemeanor for such an officer, employee or agent to prevent or attempt to prevent a
76 patient from accessing an individualized investigational treatment if the same
77 requirements are met.

78 Sections 1.6 and 1.9 revise the requirements concerning the informed, written
79 consent that a physician is required to obtain before prescribing or recommending an
80 individualized investigational treatment or an investigational drug, biological product or
81 device. Sections 1.6 and 1.9 also require a physician who prescribes or recommends an
82 individualized investigational treatment or an investigational drug, biological product or
83 device to provide the patient with a form that contains certain information concerning:
84 (1) the individualized investigational treatment or investigational drug, biological
85 product or device; and (2) the treatment of adverse effects or symptoms caused by the
86 individualized investigational treatment or investigational drug, biological product or
87 device. Sections 1.6 and 1.9 require such a physician to report to the Board of Medical
88 Examiners or the State Board of Osteopathic Medicine, as appropriate, if a patient dies
89 or is hospitalized as the result of using an individualized investigational treatment or
90 investigational drug, biological product or device. Sections 1.6 and 1.9 require those
91 boards to submit to the Legislature a biennial summary of the information reported to
92 those boards pursuant to sections 1.6, 1.9 and 2.7 concerning individualized
93 investigational treatments and investigational drugs, biological products and devices.
94 Sections 1.6 and 1.9 additionally authorize those boards to adopt regulations to ensure
95 the safety and efficacy of individualized investigational treatments and investigational
96 drugs, biological products and devices.

97 Existing law: (1) generally makes it a misdemeanor for any person to possess,
98 procure, obtain, process, produce, derive, manufacture, sell, offer for sale, give away or
99 otherwise furnish any drug which may not be lawfully introduced into interstate
100 commerce under the Federal Food, Drug and Cosmetic Act; and (2) exempts from that
101 criminal penalty a person who engages in certain acts to make an investigational drug or
102 biological product available when certain requirements are met. (NRS 454.351) Section
103 2.5 of this bill additionally exempts from the criminal penalty a manufacturer who
104 provides an individualized investigational treatment.

105 Existing law provides that a physician or person engaged in the practice of
106 professional nursing who procures or administers a controlled substance or dangerous
107 drug is not subject to professional discipline if the controlled substance or dangerous
108 drug is an investigative drug or biological product prescribed by a physician. (NRS
109 630.306, 632.347, 633.511) Sections 1.55, 1.7 and 1.8 of this bill additionally exempt such

persons from professional discipline if the substance is an individualized investigational treatment.

Existing law requires a collection agency, not less than 60 days before taking any action to collect a medical debt, to send by registered or certified mail to the medical debtor written notification setting forth certain information. (NRS 649.366) Section 2.3 of this bill removes the requirement that the written notification be sent by mail that is registered or certified.

Existing law provides for the payment of compensation to employees who are injured or disabled as a result of an occupational injury or disease. (Chapters 616A-616D and 617 of NRS) Existing law entitles any injured employee or a person who has been authorized by the injured employee to information from the records of an insurer or employer to the extent necessary for the proper presentation of such a claim. (NRS 616B.012) Existing regulations: (1) prescribe a process for an injured employee or person who has been authorized by the injured employee to request such information from the records of an insurer or employer; and (2) prohibit an insurer or employer from charging a fee that is more than 30 cents per page when providing the requested information. (NAC 616B.008)

Upon receiving such a request for health care records, **section 3** of this bill requires an insurer, third-party administrator or employer to furnish any health care records to the injured employee or his or her legal representative. **Section 3** authorizes an insurer, third-party administrator or employer to electronically transmit such health care records using a method of secure electronic transmission. **Section 3** prescribes the maximum amounts of fees for furnishing health care records in response to such a request, which depend on whether the records are furnished by electronic mail, through a secure electronic method of file sharing or in a nonelectronic format. **Section 4** of this bill makes a conforming change to clarify that **section 3** provides an exception to the general requirement that information obtained from an insurer or employer remain confidential.

Section 8 of this bill provides that the provisions of sections 1.55-1.9, 2.5 and 2.7 expire on July 1, 2027. Section 6 of this bill authorizes a patient who is being treated with an individualized investigational treatment or an investigational drug, biological product or device on June 30, 2027, to continue to receive such treatment on and after July 1, 2027, regardless of whether the patient remains eligible to receive such treatment.

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

Section 1. Chapter 629 of NRS is hereby amended by adding thereto a new section to read as follows:

1. If a person who is authorized to request a copy of health care records of a patient pursuant to NRS 629.061 requests that a copy of such records be furnished electronically, the custodian of health care records must electronically transmit a copy of the requested records to the person or, if the patient has provided written authorization for records to be furnished to another person or entity, to that person or entity. Such records must be furnished in an electronic format using a method of secure electronic transmission that complies with applicable federal and state law.

2. Except as otherwise provided in subsections 3 and 4, if a custodian of health care records maintains health care records electronically, any fee to furnish those records electronically pursuant to subsection 1 must not exceed \$40 or the amount per page prescribed by NRS 629.061, whichever is less.

3. If the total amount of the fee chargeable pursuant to subsection 2 for the furnishing of health care records electronically is less than \$5, a custodian of health care records, other than a custodian of the health care records of a state or

1 *local governmental entity, may charge a fee of \$5 for the furnishing of those*
2 *health care records.*

3 *4. A custodian of health care records, other than a custodian of the health*
4 *care records of a state or local governmental entity, may charge the following*
5 *fees to furnish health care records electronically, in addition to the total amount*
6 *of the fee charged pursuant to subsection 2 or 3:*

7 *(a) A fee of \$5 for written confirmation that no health care records were*
8 *found.*

9 *(b) A fee of \$5 for furnishing a copy of a certificate of the custodian of*
10 *health care records.*

11 *(c) A fee of \$20 for a copy of a printed film sheet.*

12 *(d) A fee of \$25 for furnishing a copy of radiologic images in any form other*
13 *than a printed film sheet.*

14 *5. As used in this section:*

15 *(a) "Custodian of health care records" has the meaning ascribed to it in NRS*
16 *629.016 and additionally includes a covered entity or business associate, as those*
17 *terms are defined in 45 C.F.R. § 160.103.*

18 *(b) "Health care records" has the meaning ascribed to it in NRS 629.021 and*
19 *additionally includes individually identifiable health information, as defined in*
20 *45 C.F.R. § 160.103.*

21 *(c) "Secure electronic transmission" means the sending of information from*
22 *one computer system to another computer system in such a manner as to ensure*
23 *that:*

24 *(1) No person other than the intended recipient receives the information;*

25 *(2) The identity and signature of the sender of the information can be*
26 *authenticated; and*

27 *(3) The information which is received by the intended recipient is*
28 *identical to the information that was sent.*

29 **Sec. 1.5.** NRS 629.171 is hereby amended to read as follows:

30 629.171 It is unlawful to disclose or to compel a person to disclose the
31 identity of a person who was the subject of a genetic test or to disclose genetic
32 information of that person in a manner that allows identification of the person,
33 without first obtaining the informed consent of that person or his or her legal
34 guardian pursuant to NRS 629.181, unless the information is disclosed:

35 1. To conduct a criminal investigation, an investigation concerning the death
36 of a person or a criminal or juvenile proceeding;

37 2. To determine the parentage or identity of a person pursuant to NRS 56.020;

38 3. To determine the paternity of a person pursuant to NRS 126.121 or
39 425.384;

40 4. Pursuant to an order of a court of competent jurisdiction;

41 5. By a physician and is the genetic information of a deceased person that will
42 assist in the medical diagnosis of persons related to the deceased person by blood;

43 6. To a federal, state, county or city law enforcement agency to establish the
44 identity of a person or dead human body;

45 7. To determine the presence of certain preventable or inheritable disorders in
46 an infant pursuant to NRS 442.008 or a provision of federal law;

47 8. To carry out the provisions of NRS 442.300 to 442.330, inclusive; ~~or~~

48 9. By an agency of criminal justice pursuant to NRS 179A.075 ~~or~~; or

49 *10. As permitted by the Health Insurance Portability and Accountability Act*
50 *of 1996, Public Law 104-191, and the regulations adopted pursuant thereto.*

51 **Sec. 1.55.** NRS 630.306 is hereby amended to read as follows:

1 630.306 1. The following acts, among others, constitute grounds for
2 initiating disciplinary action or denying licensure:

3 (a) Inability to practice medicine with reasonable skill and safety because of
4 illness, a mental or physical condition or the use of alcohol, drugs, narcotics or any
5 other substance.

6 (b) Engaging in any conduct:

7 (1) Which is intended to deceive;

8 (2) Which the Board has determined is a violation of the standards of
9 practice established by regulation of the Board; or

10 (3) Which is in violation of a provision of chapter 639 of NRS, or a
11 regulation adopted by the State Board of Pharmacy pursuant thereto, that is
12 applicable to a licensee who is a practitioner, as defined in NRS 639.0125.

13 (c) Administering, dispensing or prescribing any controlled substance, or any
14 dangerous drug as defined in chapter 454 of NRS, to or for himself or herself or to
15 others except as authorized by law.

16 (d) Performing, assisting or advising the injection of any substance containing
17 liquid silicone into the human body, except for the use of silicone oil to repair a
18 retinal detachment.

19 (e) Practicing or offering to practice beyond the scope permitted by law or
20 performing services which the licensee knows or has reason to know that he or she
21 is not competent to perform or which are beyond the scope of his or her training.

22 (f) Performing, without first obtaining the informed consent of the patient or
23 the patient's family, any procedure or prescribing any therapy which by the current
24 standards of the practice of medicine is experimental.

25 (g) Continual failure to exercise the skill or diligence or use the methods
26 ordinarily exercised under the same circumstances by physicians in good standing
27 practicing in the same specialty or field.

28 (h) Having an alcohol or other substance use disorder.

29 (i) Making or filing a report which the licensee or applicant knows to be false
30 or failing to file a record or report as required by law or regulation.

31 (j) Failing to comply with the requirements of NRS 630.254.

32 (k) Failure by a licensee or applicant to report in writing, within 30 days, any
33 disciplinary action taken against the licensee or applicant by another state, the
34 Federal Government or a foreign country, including, without limitation, the
35 revocation, suspension or surrender of a license to practice medicine in another
36 jurisdiction. The provisions of this paragraph do not apply to any disciplinary
37 action taken by the Board or taken because of any disciplinary action taken by the
38 Board.

39 (l) Failure by a licensee or applicant to report in writing, within 30 days, any
40 criminal action taken or conviction obtained against the licensee or applicant, other
41 than a minor traffic violation, in this State or any other state or by the Federal
42 Government, a branch of the Armed Forces of the United States or any local or
43 federal jurisdiction of a foreign country.

44 (m) Failure to be found competent to practice medicine as a result of an
45 examination to determine medical competency pursuant to NRS 630.318.

46 (n) Operation of a medical facility at any time during which:

47 (1) The license of the facility is suspended or revoked; or

48 (2) An act or omission occurs which results in the suspension or revocation
49 of the license pursuant to NRS 449.160.

50 ➤ This paragraph applies to an owner or other principal responsible for the
51 operation of the facility.

52 (o) Failure to comply with the requirements of NRS 630.373.

1 (p) Engaging in any act that is unsafe or unprofessional conduct in accordance
2 with regulations adopted by the Board.

3 (q) Knowingly or willfully procuring or administering a controlled substance
4 or a dangerous drug as defined in chapter 454 of NRS that is not approved by the
5 United States Food and Drug Administration, unless the unapproved controlled
6 substance or dangerous drug:

7 (1) Was procured through a retail pharmacy licensed pursuant to chapter
8 639 of NRS;

9 (2) Was procured through a Canadian pharmacy which is licensed pursuant
10 to chapter 639 of NRS and which has been recommended by the State Board of
11 Pharmacy pursuant to subsection 4 of NRS 639.2328;

12 (3) Is cannabis being used for medical purposes in accordance with chapter
13 678C of NRS; or

14 (4) Is an individualized investigational treatment or investigational drug
15 or biological product prescribed to a patient pursuant to NRS 630.3735 or
16 633.6945.

17 (r) Failure to supervise adequately a medical assistant pursuant to the
18 regulations of the Board.

19 (s) Failure to comply with the provisions of NRS 630.3745.

20 (t) Failure to obtain any training required by the Board pursuant to NRS
21 630.2535.

22 (u) Failure to comply with the provisions of NRS 454.217 or 629.086.

23 (v) Failure to comply with the provisions of NRS 441A.315 or any regulations
24 adopted pursuant thereto.

25 (w) Performing or supervising the performance of a pelvic examination in
26 violation of NRS 629.085.

27 2. As used in this section ~~["investigational"]~~ :

28 (a) "Individualized investigational treatment" has the meaning ascribed to it
29 in NRS 454.690.

30 (b) "Investigational drug or biological product" has the meaning ascribed to it
31 in NRS 454.351.

32 Sec. 1.6. NRS 630.3735 is hereby amended to read as follows:

33 630.3735 1. A physician may prescribe or recommend an individualized
34 investigational treatment or investigational drug, biological product or device to a
35 patient if the physician has:

36 (a) Diagnosed the patient with a ~~terminal~~ life-threatening or severely
37 debilitating disease or condition;

38 (b) Discussed with the patient all available methods of treating the ~~terminal~~
39 life-threatening or severely debilitating disease or condition that have been
40 approved by the United States Food and Drug Administration and the patient and
41 the physician have determined that no such method of treatment is adequate to treat
42 the ~~terminal~~ life-threatening or severely debilitating disease or condition of the
43 patient; ~~and~~

44 (c) For an individualized investigational treatment, conducted an analysis of
45 the patient's genomic sequence, human chromosomes, deoxyribonucleic acid,
46 ribonucleic acid, genes, gene products or metabolites or an immunity panel, as
47 applicable to the individualized investigational treatment; and

48 (d) Obtained informed, written consent to the use of the individualized
49 investigational treatment or investigational drug, biological product or device , as
50 applicable, from:

51 (1) The patient;

52 (2) If the patient is incompetent, the representative of the patient; or

1 (3) If the patient is less than 18 years of age, a parent or legal guardian of
2 the patient.

3 2. An informed, written consent must be recorded on a form signed by the
4 patient, or the representative or parent or legal guardian of the patient, as applicable
5 ~~of that contains:~~ The form must:

6 (a) ~~[(A)]~~ To the extent practicable, be in the preferred language of the
7 patient, or the representative or parent or legal guardian of the patient, as
8 applicable.

9 (b) Be in language that is at the reading level of an eighth grader or a pupil
10 enrolled in a lower grade.

11 (c) Include or be accompanied by:

12 (1) An overview of the provisions of this section and NRS 454.690,
13 including, without limitation, a detailed description of the provisions of
14 subsection 1 and the terms defined in subsection 8;

15 (2) A comprehensive explanation of all methods of treating the ~~terminal~~
16 life-threatening or severely debilitating disease or condition of the patient that are
17 currently approved by the United States Food and Drug Administration, ~~and~~,
18 including, without limitation, information concerning such methods published by
19 the United States Food and Drug Administration, the National Institutes of
20 Health or other federal agencies;

21 ~~[(B)]~~ (3) A statement that the patient, or the representative or parent or legal
22 guardian of the patient, as applicable, and the physician agree that no such method
23 is likely to ~~significantly prolong the life~~ adequately treat the life-threatening or
24 severely debilitating disease or condition of the patient;

25 ~~[(C)]~~ (4) Clear identification of the specific individualized investigational
26 treatment or investigational drug, biological product or device proposed to treat the
27 ~~terminal~~ life-threatening or severely debilitating disease or condition of the
28 patient;

29 ~~[(D)]~~ (5) A detailed description of the consequences of using the individualized
30 investigational treatment or investigational drug, biological product or device,
31 which must include, without limitation:

32 ~~[(1)]~~ (I) A detailed description of the best and worst possible outcomes;

33 ~~[(2)]~~ (II) A realistic and detailed description of the most likely outcome, in
34 the opinion of the physician;

35 (III) A detailed description of relevant information that is not known
36 about the individualized investigational treatment or investigational drug,
37 biological product or device; and

38 ~~[(3)]~~ (IV) A statement of the possibility that using the individualized
39 investigational treatment or investigational drug, biological product or device may
40 result in new, unanticipated, different or worse symptoms or the death of the patient
41 occurring sooner than if the individualized investigational treatment or
42 investigational drug, biological product or device is not used ~~and~~ and a detailed
43 description of any known new, different or worse symptoms the patient may
44 suffer;

45 (6) A statement of the rights of the patient, including, without limitation,
46 the rights to:

47 (I) Make an informed decision concerning the use of the
48 individualized investigational treatment or investigational drug, biological
49 product or device; and

50 (II) Withdraw from or refuse treatment using the individualized
51 investigational treatment or investigational drug, biological product or device at
52 any time;

1 (7) Information concerning resources that may be useful to the patient,
2 including, without limitation, the contact information for agencies or
3 organizations that may be able to provide support to the patient;

4 (8) A means by which the patient may contact the manufacturer of the
5 individualized investigational treatment or investigational drug, biological
6 product or device with any additional questions or concerns;

7 ~~(9)~~ (9) A statement that a health insurer of the patient may not be required to
8 pay for care or treatment of any condition resulting from the use of the
9 individualized investigational treatment or investigational drug, biological product
10 or device unless such care or treatment is specifically included in the policy of
11 insurance covering the patient and that future benefits under the policy of insurance
12 covering the patient may be affected by the patient's use of the individualized
13 investigational treatment or investigational drug, biological product or device; and

14 ~~(10)~~ (10) A statement that the patient, or the representative or parent or legal
15 guardian of the patient, as applicable, understands that the patient is liable for all
16 costs resulting from the use of the individualized investigational treatment or
17 investigational drug, biological product or device, including, without limitation,
18 costs resulting from care or treatment of any condition resulting from the use of the
19 individualized investigational treatment or investigational drug, biological product
20 or device, and that such liability will be passed on to the estate of the patient upon
21 the death of the patient.

22 3. A physician who prescribes or recommends an individualized
23 investigational treatment or investigational drug, biological product or device to a
24 patient shall provide to the patient a form that:

25 (a) To the extent practicable, is in the preferred language of the patient; and

26 (b) Contains:

27 (1) The name of the individualized investigational treatment or
28 investigational drug, biological product or device;

29 (2) The instructions for use and, where applicable, the recommended
30 dosage of the individualized investigational treatment or investigational drug,
31 biological product or device;

32 (3) Where applicable, the investigational new drug number assigned by
33 the United States Food and Drug Administration;

34 (4) The telephone number for the hotline established pursuant to
35 subsection 4 of NRS 454.690;

36 (5) The contact information, telephone number, hours of operation and
37 physical address of an emergency room or urgent care facility that is easily
38 accessible to the patient if the patient experiences an adverse effect or symptom;
39 and

40 (6) Any other information concerning the individualized investigational
41 treatment or investigational drug, biological product or device that is relevant to
42 the care of the patient.

43 4. Not later than 72 hours after the death or hospitalization of a patient
44 which results from the use of an individualized investigational treatment or
45 investigational drug, biological product or device, the physician who prescribed
46 or recommended the individualized investigational treatment or investigational
47 drug, biological product or device shall notify the Board.

48 5. On or before January 31 of each odd-numbered year, the Board shall
49 submit to the Director of the Legislative Counsel Bureau for transmittal to the
50 next regular session of the Legislature a summary of the information reported to
51 the Board pursuant to subsection 4 and subsection 4 of NRS 454.690 during the
52 immediately preceding biennium.

1 6. A physician is not subject to disciplinary action for prescribing or
2 recommending an individualized investigational treatment or investigational drug,
3 biological product or device when authorized to do so pursuant to subsection 1.

4 7. The Board may adopt regulations to ensure the safety and efficacy of
5 individualized investigational treatments and investigational drugs, biological
6 products and devices prescribed or recommended pursuant to this section.

7 ~~4~~ 8. As used in this section:

8 (a) “Individualized investigational treatment” has the meaning ascribed to it
9 in NRS 454.690.

10 (b) “Investigational drug, biological product or device” has the meaning
11 ascribed to it in NRS 454.690.

12 ~~“(b) “Terminal condition”~~

13 (c) “Life-threatening disease or condition” has the meaning ascribed to it in
14 NRS 454.690.

15 (d) “Severely debilitating disease or condition” has the meaning ascribed to
16 it in NRS 454.690.

17 Sec. 1.7. NRS 632.347 is hereby amended to read as follows:

18 632.347 1. The Board may deny, revoke or suspend any license or
19 certificate applied for or issued pursuant to this chapter, or take other disciplinary
20 action against a licensee or holder of a certificate, upon determining that the
21 licensee or certificate holder:

22 (a) Is guilty of fraud or deceit in procuring or attempting to procure a license or
23 certificate pursuant to this chapter.

24 (b) Is guilty of any offense:

25 (1) Involving moral turpitude; or

26 (2) Related to the qualifications, functions or duties of a licensee or holder
27 of a certificate,

28 ↪ in which case the record of conviction is conclusive evidence thereof.

29 (c) Has been convicted of violating any of the provisions of NRS 616D.200,
30 616D.220, 616D.240 or 616D.300 to 616D.440, inclusive.

31 (d) Is unfit or incompetent by reason of gross negligence or recklessness in
32 carrying out usual nursing functions.

33 (e) Uses any controlled substance, dangerous drug as defined in chapter 454 of
34 NRS, or intoxicating liquor to an extent or in a manner which is dangerous or
35 injurious to any other person or which impairs his or her ability to conduct the
36 practice authorized by the license or certificate.

37 (f) Is a person with mental incompetence.

38 (g) Is guilty of unprofessional conduct, which includes, but is not limited to,
39 the following:

40 (1) Conviction of practicing medicine without a license in violation of
41 chapter 630 of NRS, in which case the record of conviction is conclusive evidence
42 thereof.

43 (2) Impersonating any applicant or acting as proxy for an applicant in any
44 examination required pursuant to this chapter for the issuance of a license or
45 certificate.

46 (3) Impersonating another licensed practitioner or holder of a certificate.

47 (4) Permitting or allowing another person to use his or her license or
48 certificate to practice as a licensed practical nurse, registered nurse, nursing
49 assistant or medication aide - certified.

50 (5) Repeated malpractice, which may be evidenced by claims of
51 malpractice settled against the licensee or certificate holder.

52 (6) Physical, verbal or psychological abuse of a patient.

1 (7) Conviction for the use or unlawful possession of a controlled substance
2 or dangerous drug as defined in chapter 454 of NRS.

3 (h) Has willfully or repeatedly violated the provisions of this chapter. The
4 voluntary surrender of a license or certificate issued pursuant to this chapter is
5 prima facie evidence that the licensee or certificate holder has committed or expects
6 to commit a violation of this chapter.

7 (i) Is guilty of aiding or abetting any person in a violation of this chapter.

8 (j) Has falsified an entry on a patient's medical chart concerning a controlled
9 substance.

10 (k) Has falsified information which was given to a physician, pharmacist,
11 podiatric physician or dentist to obtain a controlled substance.

12 (l) Has knowingly procured or administered a controlled substance or a
13 dangerous drug as defined in chapter 454 of NRS that is not approved by the United
14 States Food and Drug Administration, unless the unapproved controlled substance
15 or dangerous drug:

16 (1) Was procured through a retail pharmacy licensed pursuant to chapter
17 639 of NRS;

18 (2) Was procured through a Canadian pharmacy which is licensed pursuant
19 to chapter 639 of NRS and which has been recommended by the State Board of
20 Pharmacy pursuant to subsection 4 of NRS 639.2328;

21 (3) Is cannabis being used for medical purposes in accordance with chapter
22 678C of NRS; or

23 (4) Is an *individualized investigational treatment or* investigational drug
24 or biological product prescribed to a patient pursuant to NRS 630.3735 or
25 633.6945.

26 (m) Has been disciplined in another state in connection with a license to
27 practice nursing or a certificate to practice as a nursing assistant or medication aide
28 - certified, or has committed an act in another state which would constitute a
29 violation of this chapter.

30 (n) Has engaged in conduct likely to deceive, defraud or endanger a patient or
31 the general public.

32 (o) Has willfully failed to comply with a regulation, subpoena or order of the
33 Board.

34 (p) Has operated a medical facility at any time during which:

35 (1) The license of the facility was suspended or revoked; or

36 (2) An act or omission occurred which resulted in the suspension or
37 revocation of the license pursuant to NRS 449.160.

38 ➤ This paragraph applies to an owner or other principal responsible for the
39 operation of the facility.

40 (q) Is an advanced practice registered nurse who has failed to obtain any
41 training required by the Board pursuant to NRS 632.2375.

42 (r) Is an advanced practice registered nurse who has failed to comply with the
43 provisions of NRS 453.163, 453.164, 453.226, 639.23507, 639.23535 and 639.2391
44 to 639.23916, inclusive, and any regulations adopted by the State Board of
45 Pharmacy pursuant thereto.

46 (s) Has engaged in the fraudulent, illegal, unauthorized or otherwise
47 inappropriate prescribing, administering or dispensing of a controlled substance
48 listed in schedule II, III or IV.

49 (t) Has violated the provisions of NRS 454.217 or 629.086.

50 (u) Has performed or supervised the performance of a pelvic examination in
51 violation of NRS 629.085.

1 (v) Has failed to comply with the provisions of NRS 441A.315 or any
2 regulations adopted pursuant thereto.

3 2. For the purposes of this section, a plea or verdict of guilty or guilty but
4 mentally ill or a plea of nolo contendere constitutes a conviction of an offense. The
5 Board may take disciplinary action pending the appeal of a conviction.

6 3. A licensee or certificate holder is not subject to disciplinary action solely
7 for administering auto-injectable epinephrine pursuant to a valid order issued
8 pursuant to NRS 630.374 or 633.707.

9 4. As used in this section ~~“investigational”~~;
10 (a) “Individualized investigational treatment” has the meaning ascribed to it
11 in NRS 454.690.

12 (b) “Investigational” drug or biological product” has the meaning ascribed to it
13 in NRS 454.351.

14 **Sec. 1.8. NRS 633.511 is hereby amended to read as follows:**

15 633.511 1. The grounds for initiating disciplinary action pursuant to this
16 chapter are:

17 (a) Unprofessional conduct.

18 (b) Conviction of:

19 (1) A violation of any federal or state law regulating the possession,
20 distribution or use of any controlled substance or any dangerous drug as defined in
21 chapter 454 of NRS;

22 (2) A felony relating to the practice of osteopathic medicine or practice as
23 a physician assistant;

24 (3) A violation of any of the provisions of NRS 616D.200, 616D.220,
25 616D.240 or 616D.300 to 616D.440, inclusive;

26 (4) Murder, voluntary manslaughter or mayhem;

27 (5) Any felony involving the use of a firearm or other deadly weapon;

28 (6) Assault with intent to kill or to commit sexual assault or mayhem;

29 (7) Sexual assault, statutory sexual seduction, incest, lewdness, indecent
30 exposure or any other sexually related crime;

31 (8) Abuse or neglect of a child or contributory delinquency; or

32 (9) Any offense involving moral turpitude.

33 (c) The suspension of a license to practice osteopathic medicine or to practice
34 as a physician assistant by any other jurisdiction.

35 (d) Malpractice or gross malpractice, which may be evidenced by a claim of
36 malpractice settled against a licensee.

37 (e) Professional incompetence.

38 (f) Failure to comply with the requirements of NRS 633.527.

39 (g) Failure to comply with the requirements of subsection 3 of NRS 633.471.

40 (h) Failure to comply with the provisions of NRS 633.694.

41 (i) Operation of a medical facility, as defined in NRS 449.0151, at any time
42 during which:

43 (1) The license of the facility is suspended or revoked; or

44 (2) An act or omission occurs which results in the suspension or revocation
45 of the license pursuant to NRS 449.160.

46 ➤ This paragraph applies to an owner or other principal responsible for the
47 operation of the facility.

48 (j) Failure to comply with the provisions of subsection 2 of NRS 633.322.

49 (k) Signing a blank prescription form.

50 (l) Knowingly or willfully procuring or administering a controlled substance or
51 a dangerous drug as defined in chapter 454 of NRS that is not approved by the

1 United States Food and Drug Administration, unless the unapproved controlled
2 substance or dangerous drug:

3 (1) Was procured through a retail pharmacy licensed pursuant to chapter
4 639 of NRS;

5 (2) Was procured through a Canadian pharmacy which is licensed pursuant
6 to chapter 639 of NRS and which has been recommended by the State Board of
7 Pharmacy pursuant to subsection 4 of NRS 639.2328;

8 (3) Is cannabis being used for medical purposes in accordance with chapter
9 678C of NRS; or

10 (4) Is an *individualized investigational treatment or* investigational drug
11 or biological product prescribed to a patient pursuant to NRS 630.3735 or
12 633.6945.

13 (m) Attempting, directly or indirectly, by intimidation, coercion or deception,
14 to obtain or retain a patient or to discourage the use of a second opinion.

15 (n) Terminating the medical care of a patient without adequate notice or
16 without making other arrangements for the continued care of the patient.

17 (o) In addition to the provisions of subsection 3 of NRS 633.524, making or
18 filing a report which the licensee knows to be false, failing to file a record or report
19 that is required by law or knowingly or willfully obstructing or inducing another to
20 obstruct the making or filing of such a record or report.

21 (p) Failure to report any person the licensee knows, or has reason to know, is in
22 violation of the provisions of this chapter, except for a violation of NRS 633.4717,
23 or the regulations of the Board within 30 days after the date the licensee knows or
24 has reason to know of the violation.

25 (q) Failure by a licensee or applicant to report in writing, within 30 days, any
26 criminal action taken or conviction obtained against the licensee or applicant, other
27 than a minor traffic violation, in this State or any other state or by the Federal
28 Government, a branch of the Armed Forces of the United States or any local or
29 federal jurisdiction of a foreign country.

30 (r) Engaging in any act that is unsafe in accordance with regulations adopted
31 by the Board.

32 (s) Failure to comply with the provisions of NRS 629.515.

33 (t) Failure to supervise adequately a medical assistant pursuant to the
34 regulations of the Board.

35 (u) Failure to obtain any training required by the Board pursuant to NRS
36 633.473.

37 (v) Failure to comply with the provisions of NRS 633.6955.

38 (w) Failure to comply with the provisions of NRS 453.163, 453.164, 453.226,
39 639.23507, 639.23535 and 639.2391 to 639.23916, inclusive, and any regulations
40 adopted by the State Board of Pharmacy pursuant thereto.

41 (x) Fraudulent, illegal, unauthorized or otherwise inappropriate prescribing,
42 administering or dispensing of a controlled substance listed in schedule II, III or IV.

43 (y) Failure to comply with the provisions of NRS 454.217 or 629.086.

44 (z) Failure to comply with the provisions of NRS 441A.315 or any regulations
45 adopted pursuant thereto.

46 (aa) Performing or supervising the performance of a pelvic examination in
47 violation of NRS 629.085.

48 2. As used in this section ~~the~~ *“investigational”*:

49 (a) *“Individualized investigational treatment”* has the meaning ascribed to it
50 in NRS 454.690.

51 (b) *“Investigational* drug or biological product” has the meaning ascribed to it
52 in NRS 454.351.

1 **Sec. 1.9. NRS 633.6945 is hereby amended to read as follows:**

2 633.6945 1. An osteopathic physician may prescribe or recommend an
3 **individualized investigational treatment or** investigational drug, biological product
4 or device to a patient if the osteopathic physician has:

5 (a) Diagnosed the patient with a ~~terminal~~ **life-threatening or severely**
6 **debilitating disease or** condition;

7 (b) Discussed with the patient all available methods of treating the ~~terminal~~
8 **life-threatening or severely debilitating disease or** condition that have been
9 approved by the United States Food and Drug Administration and the patient and
10 the osteopathic physician has determined that no such method of treatment is
11 adequate to treat the ~~terminal~~ **life-threatening or severely debilitating disease or**
12 condition of the patient; ~~and~~

13 (c) **For an individualized investigational treatment, conducted an analysis of**
14 **the patient's genomic sequence, human chromosomes, deoxyribonucleic acid,**
15 **ribonucleic acid, genes, gene products or metabolites or an immunity panel, as**
16 **applicable to the individualized investigational treatment; and**

17 (d) Obtained informed, written consent to the use of the **individualized**
18 **investigational treatment or** investigational drug, biological product or device, **as**
19 **applicable**, from:

20 (1) The patient;

21 (2) If the patient is incompetent, the representative of the patient; or

22 (3) If the patient is less than 18 years of age, a parent or legal guardian of
23 the patient.

24 2. An informed, written consent must be recorded on a form signed by the
25 patient, or the representative or parent or legal guardian of the patient, as applicable

26 ~~that contains:~~ **The form must:**

27 (a) ~~Be~~ **To the extent practicable, be in the preferred language of the**
28 **patient, or the representative or parent or legal guardian of the patient, as**
29 **applicable.**

30 (b) **Be in language that is at the reading level of an eighth grader or a pupil**
31 **enrolled in a lower grade.**

32 (c) **Include or be accompanied by:**

33 (1) **An overview of the provisions of this section and NRS 454.690,**
34 **including, without limitation, a detailed description of the provisions of**
35 **subsection 1 and the terms defined in subsection 8;**

36 (2) **A comprehensive** explanation of all methods of treating the ~~terminal~~
37 **life-threatening or severely debilitating disease or condition** of the patient that are
38 currently approved by the United States Food and Drug Administration ~~that~~,
39 **including, without limitation, information concerning such methods published by**
40 **the United States Food and Drug Administration, the National Institutes of**
41 **Health or other federal agencies;**

42 ~~(b)~~ (3) A statement that the patient, or the representative or parent or legal
43 guardian of the patient, as applicable, and the osteopathic physician agree that no
44 such method is likely to ~~significantly prolong the life~~ **adequately treat the life-**
45 **threatening or severely debilitating disease or condition** of the patient;

46 ~~(c)~~ (4) Clear identification of the specific **individualized investigational**
47 **treatment or** investigational drug, biological product or device proposed to treat the
48 ~~terminal~~ **life-threatening or severely debilitating disease or** condition of the
49 patient;

50 ~~(d)~~ (5) A **detailed** description of the consequences of using the **individualized**
51 **investigational treatment or** investigational drug, biological product or device,
52 which must include, without limitation:

1 ~~(I)~~ (I) A detailed description of the best and worst possible outcomes;
2 ~~(II)~~ (II) A realistic and detailed description of the most likely outcome, in
3 the opinion of the osteopathic physician;

4 (III) A detailed description of relevant information that is not known
5 about the individualized investigational treatment or investigational drug,
6 biological product or device; and

7 ~~(IV)~~ (IV) A statement of the possibility that using the individualized
8 investigational treatment or investigational drug, biological product or device may
9 result in new, unanticipated, different or worse symptoms or the death of the patient
10 occurring sooner than if the individualized investigational treatment or
11 investigational drug, biological product or device is not used ~~and a detailed~~
12 description of any known new, different or worse symptoms the patient may
13 suffer;

14 (6) A statement of the rights of the patient, including, without limitation,
15 the rights to:

16 (I) Make an informed decision concerning the use of the
17 individualized investigational treatment or investigational drug, biological
18 product or device; and

19 (II) Withdraw from or refuse treatment using the individualized
20 investigational treatment or investigational drug, biological product or device at
21 any time;

22 (7) Information concerning resources that may be useful to the patient,
23 including, without limitation, the contact information for agencies or
24 organizations that may be able to provide support to the patient;

25 (8) A means by which the patient may contact the manufacturer of the
26 individualized investigational treatment or investigational drug, biological
27 product or device with any additional questions or concerns;

28 ~~(9)~~ (9) A statement that a health insurer of the patient may not be required to
29 pay for care or treatment of any condition resulting from the use of the
30 individualized investigational treatment or investigational drug, biological product
31 or device unless such care or treatment is specifically included in the policy of
32 insurance covering the patient and that future benefits under the policy of insurance
33 covering the patient may be affected by the patient's use of the individualized
34 investigational treatment or investigational drug, biological product or device; and

35 ~~(10)~~ (10) A statement that the patient, or the representative or parent or legal
36 guardian of the patient, as applicable, understands that the patient is liable for all
37 costs resulting from the use of the individualized investigational treatment or
38 investigational drug, biological product or device, including, without limitation,
39 costs resulting from care or treatment of any condition resulting from the use of the
40 individualized investigational treatment or investigational drug, biological product
41 or device, and that such liability will be passed on to the estate of the patient upon
42 the death of the patient.

43 3. An osteopathic physician who prescribes or recommends an
44 individualized investigational treatment or investigational drug, biological
45 product or device to a patient shall provide to the patient a form that:

46 (a) To the extent practicable, is in the preferred language of the patient; and

47 (b) Contains:

48 (1) The name of the individualized investigational treatment or
49 investigational drug, biological product or device;

50 (2) The instructions for use and, where applicable, the recommended
51 dosage of the individualized investigational treatment or investigational drug,
52 biological product or device;

1 (3) Where applicable, the investigational new drug number assigned by
2 the United States Food and Drug Administration;

3 (4) The telephone number for the hotline established pursuant to
4 subsection 4 of NRS 454.690;

5 (5) The contact information, telephone number, hours of operation and
6 physical address of an emergency room or urgent care facility that is easily
7 accessible to the patient if the patient experiences an adverse effect or symptom;
8 and

9 (6) Any other information concerning the individualized investigational
10 treatment or investigational drug, biological product or device that is relevant to
11 the care of the patient.

12 4. Not later than 72 hours after the death or hospitalization of a patient
13 which results from the use of an individualized investigational treatment or
14 investigational drug, biological product or device, the osteopathic physician who
15 prescribed or recommended the individualized investigational treatment or
16 investigational drug, biological product or device shall notify the Board.

17 5. On or before January 31 of each odd-numbered year, the Board shall
18 submit to the Director of the Legislative Counsel Bureau for transmittal to the
19 next regular session of the Legislature a summary of the information reported to
20 the Board pursuant to subsection 4 and subsection 4 of NRS 454.690 during the
21 immediately preceding biennium.

22 6. An osteopathic physician is not subject to disciplinary action for
23 prescribing or recommending an individualized investigational treatment or
24 investigational drug, biological product or device when authorized to do so
25 pursuant to subsection 1.

26 7. The Board may adopt regulations to ensure the safety and efficacy of
27 individualized investigational treatments and investigational drugs, biological
28 products and devices prescribed or recommended pursuant to this section.

29 ~~4-4~~ 8. As used in this section:

30 (a) “Individualized investigational treatment” has the meaning ascribed to it
31 in NRS 454.690.

32 (b) “Investigational drug, biological product or device” has the meaning
33 ascribed to it in NRS 454.690.

34 ~~[(b) “Terminal condition”]~~

35 (c) “Life-threatening disease or condition” has the meaning ascribed to it in
36 NRS 454.690.

37 (d) “Severely debilitating disease or condition” has the meaning ascribed to
38 it in NRS 454.690.

39 **Sec. 2.** NRS 641.2291 is hereby amended to read as follows:

40 641.2291 1. A program of education for mental health professionals
41 approved by the Board, a mental health professional or a person receiving training
42 for mental health professionals is not required to retain a recording of the provision
43 of mental health services by a psychologist to a patient that meets the requirements
44 of subsection 2 if:

45 (a) The recording is used for a training activity that is part of a program of
46 education for mental health professionals approved by the Board;

47 (b) The patient has provided informed consent in writing on a form that meets
48 the requirements prescribed by the Board pursuant to subsection 3 to the use of the
49 recording in the training activity;

50 (c) Destroying the recording does not result in noncompliance with the
51 obligations described in subsection 4; and

1 (d) The recording is destroyed after the expiration of the period of time
2 prescribed by the Board pursuant to paragraph (b) of subsection 3.

3 2. A recording of the provision of mental health services by a psychologist to
4 a patient used for the purpose described in paragraph (a) of subsection 1:

5 (a) Must meet all requirements of the Health Insurance Portability and
6 Accountability Act of 1996, Public Law 104-191, and any regulations adopted
7 pursuant thereto, that are designed to prevent the reproduction, copying or theft of
8 the recording; and

9 (b) Must not contain any personally identifiable information relating to the
10 patient unless the patient has provided informed consent in writing specifically
11 authorizing the inclusion of that information in the recording.

12 3. The Board shall adopt regulations:

13 (a) Prescribing requirements governing the provision of informed written
14 consent pursuant to paragraph (b) of subsection 1, including, without limitation,
15 requirements governing:

16 (1) The form on which such informed written consent must be provided;
17 and

18 (2) The length of time that a psychologist who obtains such informed
19 written consent must maintain the informed written consent;

20 (b) Prescribing the length of time that a program of education for mental health
21 professionals, a mental health professional or a person receiving training for mental
22 health professionals that uses a recording of the provision of mental health services
23 by a psychologist to a patient for the purposes described in paragraph (a) of
24 subsection 1 may retain the recording before destroying it; and

25 (c) Defining “training activity” for the purposes of this section.

26 4. The provisions of this section do not abrogate, alter or otherwise affect the
27 obligation of a psychologist to comply with the applicable requirements of chapter
28 629 of NRS, including, without limitation, the requirement to retain records
29 concerning the mental health services that he or she provides to patients in
30 accordance with NRS 629.051 to 629.069, inclusive ~~§~~, **and section 1 of this act.**

31 5. Except where necessary for compliance with subsection 4, a recording of
32 the provision of mental health services by a psychologist to a patient that is used for
33 a training activity by a program of education for mental health professionals, a
34 mental health professional or a person receiving training for mental health
35 professionals in accordance with the provisions of this section is not a health care
36 record for the purposes of chapter 629 of NRS.

37 6. As used in this section, “mental health professional” means a psychologist,
38 a marriage and family therapist, a clinical professional counselor, a social worker, a
39 master social worker, an independent social worker, a clinical social worker, a
40 clinical alcohol and drug counselor, an alcohol and drug counselor or problem
41 gambling counselor.

42 **Sec. 2.3. NRS 649.366 is hereby amended to read as follows:**

43 649.366 1. Not less than 60 days before taking any action to collect a
44 medical debt, a collection agency shall send by ~~registered or certified~~ mail to the
45 medical debtor written notification that sets forth:

46 (a) The name of the medical facility, provider of health care or provider of
47 emergency medical services that provided the goods or services for which the
48 medical debt is owed;

49 (b) The date on which those goods or services were provided; and

50 (c) The principal amount of the medical debt.

51 2. The written notification required by subsection 1 must:

52 (a) Identify the name of the collection agency; and

1 (b) Inform the medical debtor that, as applicable:

2 (1) The medical debt has been assigned to the collection agency for
3 collection; or

4 (2) The collection agency has otherwise obtained the medical debt for
5 collection.

6 **Sec. 2.5. NRS 454.351 is hereby amended to read as follows:**

7 454.351 1. Any person within this State who possesses, procures, obtains,
8 processes, produces, derives, manufactures, sells, offers for sale, gives away or
9 otherwise furnishes any drug which may not be lawfully introduced into interstate
10 commerce under the Federal Food, Drug and Cosmetic Act is guilty of a
11 misdemeanor.

12 2. The provisions of this section do not apply:

13 (a) To physicians licensed to practice in this State who have been authorized
14 by the United States Food and Drug Administration to possess experimental drugs
15 for the purpose of conducting research to evaluate the effectiveness of such drugs
16 and who maintain complete and accurate records of the use of such drugs and
17 submit clinical reports as required by the United States Food and Drug
18 Administration.

19 (b) To any substance which has been licensed by the State Board of Health for
20 manufacture in this State but has not been approved as a drug by the United States
21 Food and Drug Administration. The exemption granted in this paragraph does not
22 grant authority to transport such a substance out of this State.

23 (c) To any person or governmental entity who possesses, procures, obtains,
24 processes, produces, derives, manufactures, sells, offers for sale, gives away or
25 otherwise furnishes an **individualized investigational treatment or** investigational
26 drug or biological product when authorized pursuant to NRS 454.690.

27 (d) To any physician who prescribes or recommends an **individualized**
28 **investigational treatment or** investigational drug or biological product pursuant to
29 NRS 630.3735 or 633.6945.

30 3. As used in this section:

31 (a) "Biological product" has the meaning ascribed to it in NRS 454.690.

32 (b) **"Individualized investigational treatment" has the meaning ascribed to it**
33 **in NRS 454.690.**

34 (c) "Investigational drug or biological product" means a drug or biological
35 product that:

36 (1) Has successfully completed Phase I of a clinical trial;

37 (2) Has not been approved by the United States Food and Drug
38 Administration; and

39 (3) Is currently being tested in a clinical trial that has been approved by the
40 United States Food and Drug Administration.

41 **Sec. 2.7. NRS 454.690 is hereby amended to read as follows:**

42 454.690 1. The manufacturer of an investigational drug, biological product
43 or device may provide or make available the investigational drug, biological
44 product or device to a patient in this State who has been diagnosed with a ~~terminal~~
45 **life-threatening or severely debilitating disease or** condition if a physician has
46 prescribed or recommended the investigational drug, biological product or device to
47 the patient as authorized pursuant to NRS 630.3735 or 633.6945.

48 2. **The manufacturer of an individualized investigational treatment may**
49 **provide or make available the individualized investigational treatment to a patient**
50 **in this State who has been diagnosed with a life-threatening or severely**
51 **debilitating disease or condition if:**

52 (a) **The manufacturer operates within a health care institution that:**

1 (1) Operates under a Federalwide Assurance for the protection of human
2 subjects pursuant to 45 C.F.R. Part 46; and

3 (2) Is subject to all Federalwide Assurance regulations, policies and
4 guidelines, including, without limitation, renewals and updates; and

5 (b) A physician has prescribed or recommended the individualized
6 investigational treatment to the patient as authorized pursuant to NRS 630.3735
7 or 633.6945.

8 3. A manufacturer who provides or makes available an individualized
9 investigational treatment or investigational drug, biological product or device, as
10 applicable, to a patient pursuant to subsection 1 may:

11 (a) Provide the investigational drug, biological product or device to the patient
12 without charge; or

13 (b) Charge the patient only for the costs associated with the manufacture of the
14 individualized investigational treatment or investigational drug, biological product
15 or device ~~to~~, as applicable.

16 4. A manufacturer that provides or makes available an individualized
17 investigational treatment or investigational drug, biological product or device to a
18 patient pursuant to subsection 1 or 2 shall:

19 (a) Establish a hotline that operates 24 hours a day, 7 days a week, including
20 holidays, for patients who develop adverse effects or symptoms.

21 (b) On or before January 1, April 1, July 1 and October 1 of each year, or, if
22 that date falls on a Saturday, Sunday or legal holiday, the next business day
23 thereafter, submit to the Board of Medical Examiners and the State Board of
24 Osteopathic Medicine a report summarizing information concerning the
25 individualized investigational treatments or the investigational drugs, biological
26 products or devices provided or made available to patients of physicians licensed
27 by the board to which the report is submitted during the immediately preceding
28 calendar quarter. The report must include, without limitation:

29 (1) The number of patients who received the individualized
30 investigational treatment or the investigational drug, biological product or device;

31 (2) Where applicable, the average number of doses received by patients;

32 (3) The name of the individualized investigational treatment or the
33 investigational drug, biological product or device and, where applicable, the
34 investigational new drug number assigned by the United States Food and Drug
35 Administration;

36 (4) The disease or condition that the individualized investigational
37 treatment or the investigational drug, biological product or device is intended to
38 treat;

39 (5) The uses for which the individualized investigational treatment or the
40 investigational drug, biological product or device was provided or made
41 available; and

42 (6) Any known adverse effects or symptoms associated with the
43 administration of the individualized investigational treatment or the
44 investigational drug, biological product or device.

45 ~~3.5.~~ 5. An officer, employee or agent of this State shall not prevent or attempt
46 to prevent a patient from accessing an individualized investigational treatment or
47 investigational drug, biological product or device that is authorized to be provided
48 or made available to a patient pursuant to this section. Counseling, advice or a
49 recommendation from a physician consistent with medical standards of care is
50 not a violation of this subsection.

51 6. This section does not create a private cause of action against the
52 manufacturer of an individualized investigational treatment or investigational

1 drug, biological product or device, or against any other person or entity involved
2 in the care of a patient who uses an individualized investigational treatment or
3 investigational drug, biological product or device for any harm done to the
4 patient resulting from the individualized investigational treatment or
5 investigational drug, biological product or device, if the manufacturer or other
6 person or entity is complying in good faith with the provisions of this section and
7 has exercised reasonable care.

8 7. Notwithstanding any provision of law to the contrary, if a patient dies
9 while being treated with an individualized investigational treatment or
10 investigational drug, biological product or device, the heir or heirs of the
11 deceased patient must not be held personally liable for any outstanding debt
12 related to such treatment.

13 ~~8.~~ 8. A violation of any provision of this section, except for subsection 4, is
14 a misdemeanor.

15 9. If a manufacturer fails to comply with the provisions of subsection 4 and
16 such failure is not caused by excusable neglect, technical problems or other
17 extenuating circumstances, the manufacturer is liable for a civil penalty to be
18 recovered by the Attorney General in an amount of \$5,000 for each day of such
19 failure. The Attorney General shall deposit any civil penalties collected pursuant
20 to this subsection with the State Treasurer for credit to the State General Fund.

21 ~~10.~~ 10. As used in this section:

22 (a) "Biological product" has the meaning ascribed to it in 42 U.S.C. § 262.

23 (b) "Individualized investigational treatment" means a drug, biological
24 product or device that is unique to and produced exclusively for use by an
25 individual patient based on the genetic profile of the patient, including, without
26 limitation, by an analysis of the genomic sequence of the patient, human
27 chromosomes, deoxyribonucleic acid, ribonucleic acid, genes, gene products such
28 as enzymes and other types of proteins or metabolites. The term includes, without
29 limitation, individualized gene therapy, antisense oligonucleotides and
30 individualized neoantigen vaccines.

31 (c) "Investigational drug, biological product or device" means a drug,
32 biological product or device that:

33 (1) Has successfully completed Phase 1 of a clinical trial;

34 (2) Has not been approved by the United States Food and Drug
35 Administration; and

36 (3) Is currently being tested in a clinical trial that has been approved by the
37 United States Food and Drug Administration.

38 ~~(e) "Terminal condition" means an incurable and irreversible condition that,~~
39 ~~without the administration of life-sustaining treatment, will, in the opinion of the~~
40 ~~attending physician, result in death within 1 year.]~~

41 (d) "Life-threatening disease or condition" has the meaning ascribed to it in
42 21 C.F.R. § 312.81, as interpreted by any guidance of the United States Food and
43 Drug Administration.

44 (e) "Severely debilitating disease or condition" has the meaning ascribed to it
45 in 21 C.F.R. § 312.81, as interpreted by any guidance of the United States Food
46 and Drug Administration.

47 **Sec. 3.** Chapter 616B of NRS is hereby amended by adding thereto a new
48 section to read as follows:

49 1. If an injured employee or his or her legal representative requests health
50 care records from an insurer, third-party administrator or employer pursuant to
51 subsection 2 of NRS 616B.012, any other provision of chapters 616A to 616D,
52 inclusive, or chapter 617 of NRS or any regulation adopted pursuant thereto, the

1 *insurer, third-party administrator or employer shall furnish a copy of the*
2 *requested records to the injured employee or legal representative. Such records*
3 *may be furnished in an electronic format using a method of secure electronic*
4 *transmission that complies with applicable federal and state law.*

5 *2. If an insurer, third-party administrator or employer maintains health*
6 *care records electronically, any fee to furnish those records in an electronic*
7 *format pursuant to subsection 1 must not exceed:*

8 *(a) Fifteen dollars for records to be delivered by electronic mail; or*

9 *(b) Twenty-five dollars for records required to be delivered using a secure*
10 *electronic method of file sharing.*

11 *3. Any fee to furnish health care records in a form that is not electronic*
12 *pursuant to subsection 1 must not exceed 30 cents per page.*

13 *4. As used in this section:*

14 *(a) "Health care records" has the meaning ascribed to it in NRS 629.021 and*
15 *additionally includes individually identifiable health information, as defined in*
16 *45 C.F.R. § 160.103.*

17 *(b) "Secure electronic transmission" has the meaning ascribed to it in*
18 *section 1 of this act.*

19 **Sec. 4.** NRS 616B.012 is hereby amended to read as follows:

20 616B.012 1. Except as otherwise provided in this section and NRS
21 239.0115, 607.217, 616B.015, 616B.021 and 616C.205, *and section 3 of this act*,
22 information obtained from any insurer, employer or employee is confidential and
23 may not be disclosed or be open to public inspection in any manner which would
24 reveal the person's identity.

25 2. Any claimant or legal representative of the claimant is entitled to
26 information from the records of the insurer, to the extent necessary for the proper
27 presentation of a claim in any proceeding under chapters 616A to 616D, inclusive,
28 or chapter 617 of NRS.

29 3. The Division and Administrator are entitled to information from the
30 records of the insurer which is necessary for the performance of their duties. The
31 Administrator may, by regulation, prescribe the manner in which otherwise
32 confidential information may be made available to:

33 (a) Any agency of this or any other state charged with the administration or
34 enforcement of laws relating to industrial insurance, unemployment compensation,
35 public assistance or labor law and industrial relations;

36 (b) Any state or local agency for the enforcement of child support;

37 (c) The Internal Revenue Service of the Department of the Treasury;

38 (d) The Department of Taxation; and

39 (e) The State Contractors' Board in the performance of its duties to enforce the
40 provisions of chapter 624 of NRS.

41 *Information obtained in connection with the administration of a program of*
42 *industrial insurance may be made available to persons or agencies for purposes*
43 *appropriate to the operation of a program of industrial insurance.*

44 4. Upon written request made by a public officer of a local government, an
45 insurer shall furnish from its records the name, address and place of employment of
46 any person listed in its records. The request must set forth the social security
47 number of the person about whom the request is made and contain a statement
48 signed by proper authority of the local government certifying that the request is
49 made to allow the proper authority to enforce a law to recover a debt or obligation
50 owed to the local government. Except as otherwise provided in NRS 239.0115, the
51 information obtained by the local government is confidential and may not be used
52 or disclosed for any purpose other than the collection of a debt or obligation owed

1 to the local government. The insurer may charge a reasonable fee for the cost of
2 providing the requested information.

3 5. To further a current criminal investigation, the chief executive officer of
4 any law enforcement agency of this State may submit to the Administrator a written
5 request for the name, address and place of employment of any person listed in the
6 records of an insurer. The request must set forth the social security number of the
7 person about whom the request is made and contain a statement signed by the chief
8 executive officer certifying that the request is made to further a criminal
9 investigation currently being conducted by the agency. Upon receipt of a request,
10 the Administrator shall instruct the insurer to furnish the information requested.
11 Upon receipt of such an instruction, the insurer shall furnish the information
12 requested. The insurer may charge a reasonable fee to cover any related
13 administrative expenses.

14 6. Upon request by the Department of Taxation, the Administrator shall
15 provide:

16 (a) Lists containing the names and addresses of employers; and

17 (b) Other information concerning employers collected and maintained by the
18 Administrator or the Division to carry out the purposes of chapters 616A to 616D,
19 inclusive, or chapter 617 of NRS,

20 to the Department for its use in verifying returns for the taxes imposed pursuant
21 to chapters 363A, 363B, 363C and 363D of NRS. The Administrator may charge a
22 reasonable fee to cover any related administrative expenses.

23 7. Any person who, in violation of this section, discloses information
24 obtained from files of claimants or policyholders or obtains a list of claimants or
25 policyholders under chapters 616A to 616D, inclusive, or chapter 617 of NRS and
26 uses or permits the use of the list for any political purposes, is guilty of a gross
27 misdemeanor.

28 8. All letters, reports or communications of any kind, oral or written, from the
29 insurer, or any of its agents, representatives or employees are privileged and must
30 not be the subject matter or basis for any lawsuit if the letter, report or
31 communication is written, sent, delivered or prepared pursuant to the requirements
32 of chapters 616A to 616D, inclusive, or chapter 617 of NRS.

33 9. The provisions of this section do not prohibit the Administrator or the
34 Division from:

35 (a) Disclosing any nonproprietary information relating to an uninsured
36 employer or proof of industrial insurance; or

37 (b) Notifying an injured employee or the surviving spouse or dependent of an
38 injured employee of benefits to which such persons may be entitled in addition to
39 those provided pursuant to the provisions of chapters 616A to 616D, inclusive, or
40 chapter 617 of NRS but only if:

41 (1) The notification is solely for the purpose of informing the recipient of
42 benefits that are available to the recipient; and

43 (2) The content of the notification is limited to information concerning
44 services which are offered by nonprofit entities.

45 **Sec. 5. The provisions of subsection 1 of NRS 218D.380 do not apply to**
46 **any provision of this act which adds or revises a requirement to submit a**
47 **report to the Legislature.**

48 **Sec. 6. 1. A patient who is being treated with an individualized**
49 **investigational treatment or an investigational drug, biological product or**
50 **device on June 30, 2027, may continue to receive such treatment on and after**
51 **July 1, 2027, regardless of whether the patient remains eligible to receive such**
52 **treatment.**

1 2. As used in this section:

2 (a) "Individualized investigational treatment" has the meaning ascribed to
3 it in NRS 454.690, as amended by section 2.7 of this act.

4 (b) "Investigational drug, biological product or device" has the meaning
5 ascribed to it in NRS 454.690, as amended by section 2.7 of this act.

6 ~~Sec. 5.~~ *Sec. 7.* The provisions of NRS 354.599 do not apply to any
7 additional expenses of a local government that are related to the provisions of this
8 act.

9 *Sec. 8. 1. This section and sections 1.55 to 1.9, inclusive, 2.5, 2.7, 5 and*
10 6 of this act become effective on July 1, 2023.

11 2. Sections 1, 1.5, 2, 2.3, 3, 4 and 7 of this act become effective on October
12 1, 2023.

13 3. Sections 1.55 to 1.9, inclusive, 2.5 and 2.7 of this act expire by
14 limitation on July 1, 2027.