Senate Bill No. 283–Senators Pazina, Donate; Daly, Dondero Loop, Flores, D. Harris, Lange, Neal, Nguyen, Ohrenschall and Scheible

CHAPTER.....

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 and 1.9** authorize a physician to prescribe or recommend an individualized investigational treatment under similar conditions to those under which a physician is authorized to recommend an investigational drug, biological

product or device, except that **sections 1.6 and 1.9** require the physician to additionally conduct certain biochemical analyses.

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

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

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

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

Existing law provides that a physician or person engaged in the practice of professional nursing who procures or administers a controlled substance or

dangerous drug is not subject to professional discipline if the controlled substance or dangerous drug is an investigative drug or biological product prescribed by a physician. (NRS 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.

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

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

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

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

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

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

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

5. As used in this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) Engaging in any conduct:

(1) Which is intended to deceive;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) The patient;

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

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

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

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

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

(c) Include or be accompanied by:

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

(2) A comprehensive explanation of all methods of treating the ~~[terminal]~~ ***life-threatening or severely debilitating disease or*** condition of the patient that are currently approved by the United States Food and Drug Administration ~~[;]~~ ***, including, without***

limitation, information concerning such methods published by the United States Food and Drug Administration, the National Institutes of Health or other federal agencies;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) Contains:

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

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

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

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

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

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

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

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

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

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

~~[4.]~~ ***8.*** As used in this section:

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

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

~~[(b) "Terminal condition"]~~

(c) "Life-threatening disease or condition" has the meaning ascribed to it in NRS 454.690.

(d) "Severely debilitating disease or condition" has the meaning ascribed to it in NRS 454.690.

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

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

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

(b) Is guilty of any offense:

(1) Involving moral turpitude; or

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

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

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

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

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

(f) Is a person with mental incompetence.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4. As used in this section ~~[, "investigational]~~ ***:***

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

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

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

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

(a) Unprofessional conduct.

(b) Conviction of:

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

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

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

(4) Murder, voluntary manslaughter or mayhem;

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

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

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

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

(9) Any offense involving moral turpitude.

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

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

(e) Professional incompetence.

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

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

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

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

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

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

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

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

(k) Signing a blank prescription form.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) The patient;

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

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

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

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

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

(c) Include or be accompanied by:

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

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

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

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

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

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

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

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

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

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

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

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

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

(8) A means by which the patient may contact the manufacturer of the individualized investigational treatment or

investigational drug, biological product or device with any additional questions or concerns;

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

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

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

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

(b) Contains:

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

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

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

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

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

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

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

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

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

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

~~[4.]~~ ***8.*** As used in this section:

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

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

~~[(b) "Terminal condition"]~~

(c) "Life-threatening disease or condition" has the meaning ascribed to it in NRS 454.690.

(d) "Severely debilitating disease or condition" has the meaning ascribed to it in NRS 454.690.

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

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

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

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

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

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

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

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

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

3. The Board shall adopt regulations:

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

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

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

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

(c) Defining "training activity" for the purposes of this section.

4. The provisions of this section do not abrogate, alter or otherwise affect the obligation of a psychologist to comply with the applicable requirements of chapter 629 of NRS, including, without limitation, the requirement to retain records concerning the mental

health services that he or she provides to patients in accordance with NRS 629.051 to 629.069, inclusive ~~.]~~ ***, and section 1 of this act.***

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

6. As used in this section, "mental health professional" means a psychologist, a marriage and family therapist, a clinical professional counselor, a social worker, a master social worker, an independent social worker, a clinical social worker, a clinical alcohol and drug counselor, an alcohol and drug counselor or problem gambling counselor.

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

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

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

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

(c) The principal amount of the medical debt.

2. The written notification required by subsection 1 must:

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

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

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

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

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

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

2. The provisions of this section do not apply:

(a) To physicians licensed to practice in this State who have been authorized by the United States Food and Drug Administration to possess experimental drugs for the purpose of conducting

research to evaluate the effectiveness of such drugs and who maintain complete and accurate records of the use of such drugs and submit clinical reports as required by the United States Food and Drug Administration.

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

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

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

3. As used in this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) The name of the individualized investigational treatment or the investigational drug, biological product or device

and, where applicable, the investigational new drug number assigned by the United States Food and Drug Administration;

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

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

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

~~[3.]~~ ***5.*** An officer, employee or agent of this State shall not prevent or attempt to prevent a patient from accessing an ***individualized investigational treatment or*** investigational drug, biological product or device that is authorized to be provided or made available to a patient pursuant to this section. ***Counseling, advice or a recommendation from a physician consistent with medical standards of care is not a violation of this subsection.***

6. This section does not create a private cause of action against the manufacturer of an individualized investigational treatment or investigational drug, biological product or device, or against any other person or entity involved in the care of a patient who uses an individualized investigational treatment or investigational drug, biological product or device for any harm done to the patient resulting from the individualized investigational treatment or investigational drug, biological product or device, if the manufacturer or other person or entity is complying in good faith with the provisions of this section and has exercised reasonable care.

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

~~[4.]~~ ***8.*** A violation of any provision of this section ***, except for subsection 4,*** is a misdemeanor.

9. If a manufacturer fails to comply with the provisions of subsection 4 and such failure is not caused by excusable neglect, technical problems or other extenuating circumstances, the manufacturer is liable for a civil penalty to be recovered by the Attorney General in an amount of $5,000 for each day of such failure. The Attorney General shall deposit any civil penalties

collected pursuant to this subsection with the State Treasurer for credit to the State General Fund.

~~[5.]~~ ***10.*** As used in this section:

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

(b) ***"Individualized investigational treatment" means 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, including, without limitation, by an analysis of the genomic sequence of the patient, human chromosomes, deoxyribonucleic acid, ribonucleic acid, genes, gene products such as enzymes and other types of proteins or metabolites. The term includes, without limitation, individualized gene therapy, antisense oligonucleotides and individualized neoantigen vaccines.***

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

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

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

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

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

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

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

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

1. If an injured employee or his or her legal representative requests health care records from an insurer, third-party administrator or employer pursuant to subsection 2 of NRS 616B.012, any other provision of chapters 616A to 616D, inclusive, or chapter 617 of NRS or any regulation adopted pursuant thereto, the insurer, third-party administrator or employer shall furnish a copy of the requested records to the injured employee or legal representative. Such records may be furnished in an electronic format using a method of secure

electronic transmission that complies with applicable federal and state law.

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

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

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

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

4. As used in this section:

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

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

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

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

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

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

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

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

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

(d) The Department of Taxation; and

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

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

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

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

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

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

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

➥ to the Department for its use in verifying returns for the taxes imposed pursuant to chapters 363A, 363B, 363C and 363D of NRS.

The Administrator may charge a reasonable fee to cover any related administrative expenses.

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

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

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

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

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

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

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

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

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

2. As used in this section:

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

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

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

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

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

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

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