ASSEMBLY BILL NO. 164–ASSEMBLYMEN OHRENSCHALL, WHEELER, FIORE; ARAUJO, ARMSTRONG, DIAZ, DICKMAN, GARDNER, JONES, MOORE, SEAMAN, SHELTON, STEWART AND SWANK

FEBRUARY 13, 2015

JOINT SPONSORS: SENATORS WOODHOUSE, SEGERBLOM AND MANENDO

Referred to Committee on Health and Human Services

SUMMARY—Revises provisions relating to access by patients to certain investigational drugs, biological products and devices. (BDR 40-125)

FISCAL NOTE: Effect on Local Government: Increases or Newly Provides for Term of Imprisonment in County or City Jail or Detention Facility.
Effect on the State: No.

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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 public health; authorizing a manufacturer to provide or make available an investigational drug, biological product or device to certain patients under certain circumstances; prohibiting an officer, employee or agent of this State from preventing or attempting to prevent a patient from accessing such an investigational drug, biological product or device under certain circumstances; authorizing a physician to prescribe or recommend an investigational drug, biological product or device to certain persons under certain circumstances; providing a penalty; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

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 serious or immediately life-threatening illness under certain circumstances. (21 C.F.R. Part 312, Subpart I) Existing Nevada law 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. (NRS 454.351)

Section 1 of this bill authorizes the manufacturer of an investigational drug, biological product or device 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 if a physician prescribes or recommends the investigational drug, biological product or device. **Section 1** defines "investigational drug, biological product or device" as 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. **Section 1** also 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. Additionally, **section 2** of this bill removes the criminal penalty otherwise imposed against a person who engages in certain acts that make an investigational drug or biological product available when certain requirements are met.

Because a prescription or recommendation from a physician is required before a patient may obtain an investigational drug, biological product or device, **sections 3 and 8** of this bill authorize a physician to issue such a prescription or recommendation 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 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. **Sections 3 and 8** also require such informed, written consent to be provided on a form that contains certain information about the possible consequences of using the investigational drug, biological product or device. Additionally, **sections 5, 7 and 9** of this bill provide 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 investigational drug or biological product prescribed by a physician.

WHEREAS, The process to approve investigational drugs, biological products and devices often takes many years; and

WHEREAS, Patients who have a terminal condition do not have the luxury of waiting until an investigational drug, biological product or device receives final approval from the United States Food and Drug Administration; and

WHEREAS, The standards of the United States Food and Drug Administration for the use of investigational drugs, biological products and devices may deny potentially life-saving treatments to terminal patients; and

WHEREAS, This State recognizes that patients who have a terminal condition have a fundamental right to attempt to pursue the preservation of their own lives by accessing available investigational drugs, biological products and devices; and

WHEREAS, The decision to use an available investigational drug, biological product or device should be made by a patient with a terminal condition in consultation with his or her physician and is not a decision to be made by the government; now, therefore,

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

Section 1. Chapter 454 of NRS is hereby amended by adding thereto a new section to read as follows:

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 condition if a physician has prescribed or recommended the investigational drug, biological product or device to the patient as authorized pursuant to section 3 or 8 of this act.

2. A manufacturer who provides or makes available an investigational drug, biological product or device 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 investigational drug, biological product or device.

3. An officer, employee or agent of this State shall not prevent or attempt to prevent a patient from accessing an investigational drug, biological product or device that is authorized to be provided or made available to a patient pursuant to this section.

4. A violation of any provision of this section is a misdemeanor.

5. As used in this section:

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

(b) "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.

Sec. 2. 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 investigational drug or biological product when authorized pursuant to section 1 of this act.

(d) To any physician who prescribes or recommends an investigational drug or biological product pursuant to section 3 or 8 of this act.

3. As used in this section:

(a) "Biological product" has the meaning ascribed to it in section 1 of this act.

(b) "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. 3. Chapter 630 of NRS is hereby amended by adding thereto a new section to read as follows:

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

(a) Diagnosed the patient with a terminal condition;

(b) Discussed with the patient all available methods of treating the terminal 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 condition of the patient; and

(c) Obtained informed, written consent to the use of the investigational drug, biological product or device 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:

(a) An explanation of all methods of treating the terminal condition of the patient that are currently approved by the United States Food and Drug Administration;

(b) 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 of the patient;

(c) Clear identification of the specific investigational drug, biological product or device proposed to treat the terminal condition of the patient;

(d) A description of the consequences of using the investigational drug, biological product or device, which must include, without limitation:

(1) A description of the best and worst possible outcomes;

(2) A realistic description of the most likely outcome, in the opinion of the physician; and

(3) A statement of the possibility that using the 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 investigational drug, biological product or device is not used;

(e) 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 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 investigational drug, biological product or device; and

(f) 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 investigational drug, biological product or device, including, without limitation, costs resulting from care or treatment of any condition resulting from the use of the 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 is not subject to disciplinary action for prescribing or recommending an investigational drug, biological product or device when authorized to do so pursuant to subsection 1.

4. As used in this section:

(a) "Investigational drug, biological product or device" has the meaning ascribed to it in section 1 of this act.

(b) "Terminal condition" has the meaning ascribed to it in section 1 of this act.

Sec. 4. NRS 630.254 is hereby amended to read as follows:

630.254 1. Each licensee shall maintain a permanent mailing address with the Board to which all communications from the Board to the licensee must be sent. A licensee who changes his or her permanent mailing address shall notify the Board in writing of the new permanent mailing address within 30 days after the change. If a licensee fails to notify the Board in writing of a change in his or her permanent mailing address within 30 days after the change, the Board:

(a) Shall impose upon the licensee a fine not to exceed $250; and

(b) May initiate disciplinary action against the licensee as provided pursuant to ***paragraph (j) of*** subsection ~~[10]~~ ***1*** of NRS 630.306.

2. Any licensee who changes the location of his or her office in this State shall notify the Board in writing of the change before practicing at the new location.

3. Any licensee who closes his or her office in this State shall:

(a) Notify the Board in writing of this occurrence within 14 days after the closure; and

(b) For a period of 5 years thereafter, unless a longer period of retention is provided by federal law, keep the Board apprised in

writing of the location of the medical records of the licensee's patients.

4. In addition to the requirements of subsection 1, any licensee who performs any of the acts described in subsection 3 of NRS 630.020 from outside this State or the United States shall maintain an electronic mail address with the Board to which all communications from the Board to the licensee may be sent.

Sec. 5. 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:

~~[1.]~~ ***(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.

~~[2.]~~ ***(b)*** Engaging in any conduct:

~~[(a)]~~ ***(1)*** Which is intended to deceive;

~~[(b)]~~ ***(2)*** Which the Board has determined is a violation of the standards of practice established by regulation of the Board; or

~~[(c)]~~ ***(3)*** Which is in violation of a regulation adopted by the State Board of Pharmacy.

~~[3.]~~ ***(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.

~~[4.]~~ ***(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.

~~[5.]~~ ***(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.

~~[6.]~~ ***(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.

~~[7.]~~ ***(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.

~~[8.]~~ ***(h)*** Habitual intoxication from alcohol or dependency on controlled substances.

~~[9.]~~ ***(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.

~~[10.]~~ ***(j)*** Failing to comply with the requirements of NRS 630.254.

~~[11.]~~ ***(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.

~~[12.]~~ ***(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.

~~[13.]~~ ***(m)*** Failure to be found competent to practice medicine as a result of an examination to determine medical competency pursuant to NRS 630.318.

~~[14.]~~ ***(n)*** Operation of a medical facility at any time during which:

~~[(a)]~~ ***(1)*** The license of the facility is suspended or revoked; or

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

➥ This ~~[subsection]~~ ***paragraph*** applies to an owner or other principal responsible for the operation of the facility.

~~[15.]~~ ***(o)*** Failure to comply with the requirements of NRS 630.373.

~~[16.]~~ ***(p)*** Engaging in any act that is unsafe or unprofessional conduct in accordance with regulations adopted by the Board.

~~[17.]~~ ***(q)*** Knowingly 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:

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

~~[(b)]~~ ***(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; ~~[or~~

~~(c)]~~ ***(3)*** Is marijuana being used for medical purposes in accordance with chapter 453A of NRS ~~[.~~

~~18.]~~ ***; or***

(4) Is an investigational drug or biological product prescribed to a patient pursuant to section 3 or 8 of this act.

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

2. As used in this section, "investigational drug or biological product" has the meaning ascribed to it in NRS 454.351.

Sec. 6. NRS 630.30665 is hereby amended to read as follows:

630.30665 1. The Board shall require each holder of a license to practice medicine to submit to the Board, on a form provided by

the Board, a report stating the number and type of surgeries requiring conscious sedation, deep sedation or general anesthesia performed by the holder of the license at his or her office or any other facility, excluding any surgical care performed:

(a) At a medical facility as that term is defined in NRS 449.0151; or

(b) Outside of this State.

2. In addition to the report required pursuant to subsection 1, the Board shall require each holder of a license to practice medicine to submit a report to the Board concerning the occurrence of any sentinel event arising from any surgery described in subsection 1. The report must be submitted in the manner prescribed by the Board which must be substantially similar to the manner prescribed by the State Board of Health for reporting information pursuant to NRS 439.835.

3. Each holder of a license to practice medicine shall submit the reports required pursuant to subsections 1 and 2:

(a) At the time the holder of a license renews his or her license; and

(b) Whether or not the holder of the license performed any surgery described in subsection 1. Failure to submit a report or knowingly filing false information in a report constitutes grounds for initiating disciplinary action pursuant to ***paragraph (i) of*** subsection ~~[9]~~ ***1*** of NRS 630.306.

4. In addition to the reports required pursuant to subsections 1 and 2, the Board shall require each holder of a license to practice medicine to submit a report to the Board concerning the occurrence of any sentinel event arising from any surgery described in subsection 1 within 14 days after the occurrence of the sentinel event. The report must be submitted in the manner prescribed by the Board.

5. The Board shall:

(a) Collect and maintain reports received pursuant to subsections 1, 2 and 4;

(b) Ensure that the reports, and any additional documents created from the reports, are protected adequately from fire, theft, loss, destruction and other hazards, and from unauthorized access; and

(c) Submit to the Division of Public and Behavioral Health a copy of the report submitted pursuant to subsection 1. The Division shall maintain the confidentiality of such reports in accordance with subsection 6.

6. Except as otherwise provided in NRS 239.0115, a report received pursuant to subsection 1, 2 or 4 is confidential, not subject

to subpoena or discovery, and not subject to inspection by the general public.

7. The provisions of this section do not apply to surgical care requiring only the administration of oral medication to a patient to relieve the patient's anxiety or pain, if the medication is not given in a dosage that is sufficient to induce in a patient a controlled state of depressed consciousness or unconsciousness similar to general anesthesia, deep sedation or conscious sedation.

8. In addition to any other remedy or penalty, if a holder of a license to practice medicine fails to submit a report or knowingly files false information in a report submitted pursuant to this section, the Board may, after providing the holder of a license to practice medicine with notice and opportunity for a hearing, impose against the holder of a license to practice medicine an administrative penalty for each such violation. The Board shall establish by regulation a sliding scale based on the severity of the violation to determine the amount of the administrative penalty to be imposed against the holder of the license pursuant to this subsection. The regulations must include standards for determining the severity of the violation and may provide for a more severe penalty for multiple violations.

9. As used in this section:

(a) "Conscious sedation" has the meaning ascribed to it in NRS 449.436.

(b) "Deep sedation" has the meaning ascribed to it in NRS 449.437.

(c) "General anesthesia" has the meaning ascribed to it in NRS 449.438.

(d) "Sentinel event" means an unexpected occurrence involving death or serious physical or psychological injury or the risk thereof, including, without limitation, any process variation for which a recurrence would carry a significant chance of serious adverse outcome. The term includes loss of limb or function.

Sec. 7. NRS 632.320 is hereby amended to read as follows:

632.320 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; ~~[or]~~

(3) Is marijuana being used for medical purposes in accordance with chapter 453A of NRS ~~[.]~~ ***; or***

(4) Is an investigational drug or biological product prescribed to a patient pursuant to section 3 or 8 of this act.

(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.

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 drug or biological product" has the meaning ascribed to it in NRS 454.351.

Sec. 8. Chapter 633 of NRS is hereby amended by adding thereto a new section to read as follows:

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

(a) Diagnosed the patient with a terminal condition;

(b) Discussed with the patient all available methods of treating the terminal 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 condition of the patient; and

(c) Obtained informed, written consent to the use of the investigational drug, biological product or device 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:

(a) An explanation of all methods of treating the terminal condition of the patient that are currently approved by the United States Food and Drug Administration;

(b) 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 of the patient;

(c) Clear identification of the specific investigational drug, biological product or device proposed to treat the terminal condition of the patient;

(d) A description of the consequences of using the investigational drug, biological product or device, which must include, without limitation:

(1) A description of the best and worst possible outcomes;

(2) A realistic description of the most likely outcome, in the opinion of the osteopathic physician; and

(3) A statement of the possibility that using the 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 investigational drug, biological product or device is not used;

(e) 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 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 investigational drug, biological product or device; and

(f) 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 investigational drug, biological product or device, including, without limitation, costs resulting from care or treatment of any condition resulting from the use of the 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 is not subject to disciplinary action for prescribing or recommending an investigational drug, biological product or device when authorized to do so pursuant to subsection 1.

4. As used in this section:

(a) "Investigational drug, biological product or device" has the meaning ascribed to it in section 1 of this act.

(b) "Terminal condition" has the meaning ascribed to it in section 1 of this act.

Sec. 9. NRS 633.511 is hereby amended to read as follows:

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

~~[1.]~~ ***(a)*** Unprofessional conduct.

~~[2.]~~ ***(b)*** Conviction of:

~~[(a)]~~ ***(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;

~~[(b)]~~ ***(2)*** A felony relating to the practice of osteopathic medicine or practice as a physician assistant;

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

~~[(d)]~~ ***(4)*** Murder, voluntary manslaughter or mayhem;

~~[(e)]~~ ***(5)*** Any felony involving the use of a firearm or other deadly weapon;

~~[(f)]~~ ***(6)*** Assault with intent to kill or to commit sexual assault or mayhem;

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

~~[(h)]~~ ***(8)*** Abuse or neglect of a child or contributory delinquency; or

~~[(i)]~~ ***(9)*** Any offense involving moral turpitude.

~~[3.]~~ ***(c)*** The suspension of a license to practice osteopathic medicine or to practice as a physician assistant by any other jurisdiction.

~~[4.]~~ ***(d)*** Malpractice or gross malpractice, which may be evidenced by a claim of malpractice settled against a licensee.

~~[5.]~~ ***(e)*** Professional incompetence.

~~[6.]~~ ***(f)*** Failure to comply with the requirements of NRS 633.527.

~~[~~7.~~]~~ ***(g)*** Failure to comply with the requirements of subsection 3 of NRS 633.471.

~~[~~8.~~]~~ ***(h)*** Failure to comply with the provisions of NRS 633.694.

~~[~~9.~~]~~ ***(i)*** Operation of a medical facility, as defined in NRS 449.0151, at any time during which:

~~[~~(a)~~]~~ ***(1)*** The license of the facility is suspended or revoked; or

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

➥ This ~~[~~subsection~~]~~ ***paragraph*** applies to an owner or other principal responsible for the operation of the facility.

~~[~~10.~~]~~ ***(j)*** Failure to comply with the provisions of subsection 2 of NRS 633.322.

~~[~~11.~~]~~ ***(k)*** Signing a blank prescription form.

~~[~~12.~~]~~ ***(l)*** Knowingly 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:

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

~~[~~(b)~~]~~ ***(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; ~~[~~or

~~(c)~~~~]~~ ***(3)*** Is marijuana being used for medical purposes in accordance with chapter 453A of NRS ~~[~~.

~~13.~~~~]~~ ***; or***

(4) Is an investigational drug or biological product prescribed to a patient pursuant to section 3 or 8 of this act.

(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.

~~[~~14.~~]~~ ***(n)*** Terminating the medical care of a patient without adequate notice or without making other arrangements for the continued care of the patient.

~~[~~15.~~]~~ ***(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 willfully obstructing or inducing another to obstruct the making or filing of such a record or report.

~~[~~16.~~]~~ ***(p)*** Failure to report any person the licensee knows, or has reason to know, is in violation of the provisions of this chapter or the regulations of the Board within 30 days after the date the licensee knows or has reason to know of the violation.

~~[~~17.~~]~~ ***(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.

~~[18.]~~ ***(r)*** Engaging in any act that is unsafe in accordance with regulations adopted by the Board.

~~[19.]~~ ***(s)*** Failure to comply with the provisions of NRS 633.165.

~~[20.]~~ ***(t)*** Failure to supervise adequately a medical assistant pursuant to the regulations of the Board.

2. As used in this section, "investigational drug or biological product" has the meaning ascribed to it in NRS 454.351.

Sec. 10. This act becomes effective upon passage and approval.

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