SENATE BILL NO. 272-SENATOR SCHNEIDER

MARCH 16, 2009

Referred to Committee on Commerce and Labor

SUMMARY—Creates the Institutional Review Board of Nevada. (BDR 54-873)

FISCAL NOTE: Effect on Local Government: No.

Effect on the State: No.

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

AN ACT relating to health; creating the Institutional Review Board of Nevada; revising provisions related to the Nevada Institutional Review Board; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law provides for the Nevada Institutional Review Board, which is presently required to refrain from exercising its powers and which will cease to exist on June 30, 2009. (NRS 630A.800-630A.910)

Sections 2-15 of this bill create a new board named the Institutional Review Board of Nevada, which is modeled after the Nevada Institutional Review Board. However, unlike the Nevada Institutional Review Board, the Institutional Review Board of Nevada will not be under the supervision of the Board of Homeopathic Medical Examiners.

Section 16 of this bill provides that chapter 630A of NRS, which governs homeopathic medicine, does not apply to activities undertaken under the authority of the Institutional Review Board of Nevada.

Sections 23 and 24 of this bill provide that the Institutional Review Board of Nevada will receive the books, records, minutes, documents and other property of the Nevada Institutional Review Board.



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

- **Section 1.** Title 54 of NRS is hereby amended by adding thereto a new chapter to consist of the provisions set forth as sections 2 to 15, inclusive, of this act.
 - Sec. 2. As used in this chapter, unless the context otherwise requires, the words and terms defined in sections 3 to 7, inclusive, of this act have the meanings ascribed to them in those sections.
 - Sec. 3. "Advanced practitioner of homeopathy" means a person who has:
- 1. Complied with all of the requirements set forth in chapter 630A of NRS and the regulations adopted pursuant to that chapter for advanced practitioners of homeopathy; and
- 2. Received pursuant to chapter 630A of NRS a certificate as an advanced practitioner of homeopathy.
- Sec. 4. "Homeopathic medicine" or "homeopathy" means a system of medicine employing substances of animal, vegetable, chemical or mineral origin, including:
 - 1. Nosodes and sarcodes, which are:
- (a) Given in micro-dosage, except that sarcodes may be given in macro-dosage;
- (b) Prepared according to homeopathic pharmacology by which the formulation of homeopathic preparations is accomplished by the methods of Hahnemannian dilution and succussion or magnetically energized geometric patterns applicable in potencies above 30X, as defined in the official Homeopathic Pharmacopoeia of the United States; and
- (c) Prescribed by homeopathics or advanced practitioners of homeopathy according to the medicines and dosages in the Homeopathic Pharmacopoeia of the United States,
- 29 in accordance with the principle that a substance which 30 produces symptoms in a healthy person can eliminate those 31 symptoms in an ill person.
 - 2. Noninvasive electrodiagnosis, cell therapy, neural therapy, herbal therapy, neuromuscular integration, orthomolecular therapy and nutrition.
 - Sec. 5. "Practitioner" means:
 - 1. A homeopathic physician licensed pursuant to chapter 630A of NRS;
 - 2. A physician licensed pursuant to chapter 630 of NRS; or
- 39 3. An osteopathic physician licensed pursuant to chapter 633 40 of NRS.
- 41 Sec. 6. 1. "Research study" means any research, study or 42 trial using devices, therapies or substances used in homeopathic





medicine, or any combination of those devices, therapies or substances, in a manner that is considered to be a form of alternative or complementary integrative medicine.

2. The term does not include any research, study or trial

described in section 8 of this act.

Sec. 7. 1. "Researcher" means a practitioner who intends to undertake or is undertaking a research study.

2. The term does not include a practitioner who intends to undertake or is undertaking any research, study or trial described in section 8 of this act.

- Sec. 8. The provisions of this chapter do not apply to any research, study or trial that is conducted under the auspices of a federally qualified institutional review board and in accordance with applicable federal statutes.
- Sec. 9. 1. The Institutional Review Board of Nevada is hereby created.
- 2. The Institutional Review Board of Nevada consists of seven members appointed as follows:
- 19 (a) After consultation with organizations in Nevada 20 representing medical disciplines, the Governor shall appoint four 21 members who represent various medical disciplines in Nevada; 22 and
 - (b) Three members who are lay members of the general public and residents of Nevada and who are not licensed in any medical discipline must be appointed as follows:
 - (1) One member appointed by the Governor;
 - (2) One member appointed by the Majority Leader of the Senate; and
 - (3) One member appointed by the Speaker of the Assembly.
 - 3. The members of the Institutional Review Board of Nevada serve at the pleasure of the appointing authority. A vacancy on the Institutional Review Board of Nevada must be filled by the appointing authority in the same manner as the original appointment.
 - 4. The members of the Institutional Review Board of Nevada are entitled to receive, out of the money coming into the possession of the Institutional Review Board of Nevada, a per diem allowance and travel expenses, as fixed by the Institutional Review Board of Nevada.
 - 5. Four members of the Institutional Review Board of Nevada constitute a quorum. A quorum may exercise all the power and authority conferred on the Institutional Review Board of Nevada.
 - 6. The Institutional Review Board of Nevada shall elect officers from within its membership, fix the time and place of its





meetings and adopt rules of procedure as it deems necessary to carry out its duties.

- Sec. 10. Before entering upon the duties of his office, each member of the Institutional Review Board of Nevada shall take:
 - 1. The constitutional oath or affirmation of office; and
- 2. An oath or affirmation that he is legally qualified to serve on the Institutional Review Board of Nevada.
- Sec. 11. 1. Except as otherwise provided in subsection 3, the Institutional Review Board of Nevada may be funded by:
- (a) A nonprofit organization, created by the Institutional Review Board of Nevada, which is exempt from taxation pursuant to $26 \text{ U.S.C.} \S 501(c)(3)$; and
- (b) Grants, gifts, appropriations or donations to assist the Institutional Review Board of Nevada in carrying out its duties pursuant to the provisions of this chapter.
- 2. Any money received by the Institutional Review Board of Nevada must be placed with the financial institutions described in section 12 of this act.
- 3. The Institutional Review Board of Nevada may not be funded by any money from:
 - (a) The sponsor of any research study; or
- 22 (b) The manufacturer of any device, drug or other substance 23 used in homeopathic medicine.
 - Sec. 12. 1. All money received by the Institutional Review Board of Nevada must be deposited in financial institutions in this State that are federally insured or insured by a private insurer approved pursuant to NRS 678.755.
 - 2. The deposited money must only be used to carry out the activities of the Institutional Review Board of Nevada and to pay the expenses incurred by the Institutional Review Board of Nevada in the discharge of its duties.
 - Sec. 13. The Institutional Review Board of Nevada shall adopt regulations to carry out the provisions of this chapter.
 - Sec. 14. 1. The Institutional Review Board of Nevada shall:
- 35 (a) Review proposals for research studies and oversee, review 36 and control all research studies it has approved;
 - (b) Evaluate, determine and act upon the safety, efficacy, reimbursement and availability of diagnostic devices, substances, other modalities, therapies and methods of treatment used in such research studies; and
 - (c) Analyze, coordinate and integrate the diagnostic techniques and treatments related to alternative and complementary integrative medicine with the diagnostic techniques and treatments of other health care practices.





- 2. The Institutional Review Board of Nevada shall oversee, review and control any research studies which it has approved and which involve the use of human research subjects and any related issues, including, without limitation:
- (a) The qualifications required for conducting such research studies;
- (b) The proper clinical outcome to be attributed to such research studies; and
- (c) The safety, efficacy, reimbursement and availability of diagnostic devices, substances, other modalities, therapies and methods of treatment used in such research studies.
 - 3. The Institutional Review Board of Nevada shall evaluate:
- (a) The social and economic impact of the research studies it has approved; and
- (b) The relationship between alternative and complementary integrative medicine and other health care practices.
- Sec. 15. 1. A researcher who intends to undertake a research study must submit a proposal for the research study to the Institutional Review Board of Nevada for its review and approval.
- 2. A researcher shall not undertake a research study unless the proposal for the research study has been approved by the Institutional Review Board of Nevada.
 - **Sec. 16.** NRS 630A.090 is hereby amended to read as follows: 630A.090 1. This chapter does not apply to:
- (a) The practice of dentistry, chiropractic, Oriental medicine, podiatry, optometry, respiratory care, faith or Christian Science healing, nursing, veterinary medicine or fitting hearing aids.
- (b) A medical officer of the Armed Services or a medical officer of any division or department of the United States in the discharge of his official duties.
- (c) Licensed or certified nurses in the discharge of their duties as
- (d) Homeopathic physicians who are called into this State, other than on a regular basis, for consultation or assistance to any physician licensed in this State, and who are legally qualified to practice in the state or country where they reside.
- (e) Any activity undertaken pursuant to sections 2 to 15, inclusive, of this act.
- 2. This chapter does not repeal or affect any statute of Nevada regulating or affecting any other healing art.
 - 3. This chapter does not prohibit:
 - (a) Gratuitous services of a person in case of emergency.
 - (b) The domestic administration of family remedies.





- 4. This chapter does not authorize a homeopathic physician to practice medicine, including allopathic medicine, except as otherwise provided in NRS 630A.040.
 - **Sec. 17.** NRS 218.825 is hereby amended to read as follows:
- 218.825 1. Except as otherwise provided in subsection 2, each board created by the provisions of NRS 590.485 and chapters 623 to 625A, inclusive, 628, 630 to 644, inclusive, 648, 654 and 656 of NRS *and sections 2 to 15, inclusive, of this act* shall:
- (a) If the revenue of the board from all sources is less than \$50,000 for any fiscal year, prepare a balance sheet for that fiscal year on the form provided by the Legislative Auditor and file the balance sheet with the Legislative Auditor and the Chief of the Budget Division of the Department of Administration on or before December 1 following the end of that fiscal year. The Legislative Auditor shall prepare and make available a form that must be used by a board to prepare such a balance sheet.
- (b) If the revenue of the board from all sources is \$50,000 or more for any fiscal year, engage the services of a certified public accountant or public accountant, or firm of either of such accountants, to audit all its fiscal records for that fiscal year and file a report of the audit with the Legislative Auditor and the Chief of the Budget Division of the Department of Administration on or before December 1 following the end of that fiscal year.
- 2. In lieu of preparing a balance sheet or having an audit conducted for a single fiscal year, a board may engage the services of a certified public accountant or public accountant, or firm of either of such accountants, to audit all its fiscal records for a period covering two successive fiscal years. If such an audit is conducted, the board shall file the report of the audit with the Legislative Auditor and the Chief of the Budget Division of the Department of Administration on or before December 1 following the end of the second fiscal year.
- 3. The cost of each audit conducted pursuant to subsection 1 or 2 must be paid by the board that is audited. Each such audit must be conducted in accordance with generally accepted auditing standards, and all financial statements must be prepared in accordance with generally accepted principles of accounting for special revenue funds.
- 4. Whether or not a board is required to have its fiscal records audited pursuant to subsection 1 or 2, the Legislative Auditor shall audit the fiscal records of any such board whenever directed to do so by the Legislative Commission. When the Legislative Commission directs such an audit, the Legislative Commission shall also determine who is to pay the cost of the audit.





- 5. A person who is a state officer or employee of a board is guilty of nonfeasance if the person:
- (a) Is responsible for preparing a balance sheet or having an audit conducted pursuant to this section or is responsible for preparing or maintaining the fiscal records that are necessary to prepare a balance sheet or have an audit conducted pursuant to this section; and
- (b) Knowingly fails to prepare the balance sheet or have the audit conducted pursuant to this section or knowingly fails to prepare or maintain the fiscal records that are necessary to prepare a balance sheet or have an audit conducted pursuant to this section.
- 6. In addition to any other remedy or penalty, a person who is guilty of nonfeasance pursuant to this section forfeits his state office or employment and may not be appointed to a state office or position of state employment for a period of 2 years following the forfeiture. The provisions of this subsection do not apply to a state officer who may be removed from office only by impeachment pursuant to Article 7 of the Nevada Constitution.
 - **Sec. 18.** NRS 284.013 is hereby amended to read as follows: 284.013 1. Except as otherwise provided in subsection 4, this

chapter does not apply to:

- (a) Agencies, bureaus, commissions, officers or personnel in the Legislative Department or the Judicial Department of State Government, including the Commission on Judicial Discipline;
- (b) Any person who is employed by a board, commission, committee or council created in chapters 590, 623 to 625A, inclusive, 628, 630 to 644, inclusive, 648, 652, 654 and 656 of NRS [] and sections 2 to 15, inclusive, of this act; or
- (c) Officers or employees of any agency of the Executive Department of the State Government who are exempted by specific statute.
- 2. Except as otherwise provided in subsection 3, the terms and conditions of employment of all persons referred to in subsection 1, including salaries not prescribed by law and leaves of absence, including, without limitation, annual leave and sick and disability leave, must be fixed by the appointing or employing authority within the limits of legislative appropriations or authorizations.
- 3. Except as otherwise provided in this subsection, leaves of absence prescribed pursuant to subsection 2 must not be of lesser duration than those provided for other state officers and employees pursuant to the provisions of this chapter. The provisions of this subsection do not govern the Legislative Commission with respect to the personnel of the Legislative Counsel Bureau.
- 4. Any board, commission, committee or council created in chapters 590, 623 to 625A, inclusive, 628, 630 to 644, inclusive,





648, 652, 654 and 656 of NRS *and sections 2 to 15, inclusive, of this act* which contracts for the services of a person, shall require the contract for those services to be in writing. The contract must be approved by the State Board of Examiners before those services may be provided.

Sec. 19. NRS 353.005 is hereby amended to read as follows:

353.005 The provisions of this chapter do not apply to boards created by the provisions of NRS 590.485 and chapters 623 to 625A, inclusive, 628, 630 to 644, inclusive, 648, 654 and 656 of NRS *and sections 2 to 15, inclusive, of this act* and the officers and employees of those boards.

Sec. 20. NRS 353A.020 is hereby amended to read as follows:

353A.020 1. The Director, in consultation with the Committee and Legislative Auditor, shall adopt a uniform system of internal accounting and administrative control for agencies. The elements of the system must include, without limitation:

- (a) A plan of organization which provides for a segregation of duties appropriate to safeguard the assets of the agency;
- (b) A plan which limits access to assets of the agency to persons who need the assets to perform their assigned duties;
- (c) Procedures for authorizations and recordkeeping which effectively control accounting of assets, liabilities, revenues and expenses;
- (d) A system of practices to be followed in the performance of the duties and functions of each agency; and
 - (e) An effective system of internal review.
- 2. The Director, in consultation with the Committee and Legislative Auditor, may modify the system whenever he considers it necessary.
- 3. Each agency shall develop written procedures to carry out the system of internal accounting and administrative control adopted pursuant to this section.
 - 4. For the purposes of this section, "agency" does not include:
- (a) A board created by the provisions of NRS 590.485 and chapters 623 to 625A, inclusive, 628, 630 to 644, inclusive, 648, 654 and 656 of NRS : and sections 2 to 15, inclusive, of this act.
 - (b) The Nevada System of Higher Education.
 - (c) The Public Employees' Retirement System.
- (d) The Housing Division of the Department of Business and Industry.
 - (e) The Colorado River Commission of Nevada.

Sec. 21. NRS 353A.025 is hereby amended to read as follows:

353A.025 1. The head of each agency shall periodically review the agency's system of internal accounting and administrative control to determine whether it is in compliance with





the uniform system of internal accounting and administrative control for agencies adopted pursuant to subsection 1 of NRS 353A.020.

- 2. On or before July 1 of each even-numbered year, the head of each agency shall report to the Director whether the agency's system of internal accounting and administrative control is in compliance with the uniform system adopted pursuant to subsection 1 of NRS 353A.020. The reports must be made available for inspection by the members of the Legislature.
 - 3. For the purposes of this section, "agency" does not include:
- (a) A board created by the provisions of NRS 590.485 and chapters 623 to 625A, inclusive, 628, 630 to 644, inclusive, 648, 654 and 656 of NRS : and sections 2 to 15, inclusive, of this act.
 - (b) The Nevada System of Higher Education.
 - (c) The Public Employees' Retirement System.
- (d) The Housing Division of the Department of Business and Industry.
 - (e) The Colorado River Commission of Nevada.
- 4. The Director shall, on or before the first Monday in February of each odd-numbered year, submit a report on the status 20 of internal accounting and administrative controls in agencies to the:
 - (a) Director of the Legislative Counsel Bureau for transmittal to the:
 - (1) Senate Standing Committee on Finance; and
 - (2) Assembly Standing Committee on Ways and Means;
 - (b) Governor; and

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- (c) Legislative Auditor.
- The report submitted by the Director pursuant to subsection 4 must include, without limitation:
- (a) The identification of each agency that has not complied with the requirements of subsections 1 and 2;
- (b) The identification of each agency that does not have an effective method for reviewing its system of internal accounting and administrative control: and
- (c) The identification of each agency that has weaknesses in its system of internal accounting and administrative control, and the extent and types of such weaknesses.
 - **Sec. 22.** NRS 353A.045 is hereby amended to read as follows: 353A.045 The Chief shall:
 - Report to the Director.
- Develop long-term and annual work plans to be based on the results of periodic documented risk assessments. The annual work plan must list the agencies to which the Division will provide training and assistance and be submitted to the Director for approval. Such agencies must not include:





- (a) A board created by the provisions of NRS 590.485 and chapters 623 to 625A, inclusive, 628, 630 to 644, inclusive, 648, 654 and 656 of NRS : and sections 2 to 15, inclusive, of this act.
 - (b) The Nevada System of Higher Education.
 - (c) The Public Employees' Retirement System.
- (d) The Housing Division of the Department of Business and Industry.
 - (e) The Colorado River Commission of Nevada.
- 3. Provide a copy of the approved annual work plan to the Legislative Auditor.
- 4. In consultation with the Director, prepare a plan for auditing executive branch agencies for each fiscal year and present the plan to the Committee for its review and approval. Each plan for auditing must:
- (a) State the agencies which will be audited, the proposed scope and assignment of those audits and the related resources which will be used for those audits; and
- (b) Ensure that the internal accounting, administrative controls and financial management of each agency are reviewed periodically.
- 5. Perform the audits of the programs and activities of the agencies in accordance with the plan approved pursuant to subsection 5 of NRS 353A.038 and prepare audit reports of his findings.
- 6. Review each agency that is audited pursuant to subsection 5 and advise those agencies concerning internal accounting, administrative controls and financial management.
- 7. Submit to each agency that is audited pursuant to subsection 5 analyses, appraisals and recommendations concerning:
- (a) The adequacy of the internal accounting and administrative controls of the agency; and
- (b) The efficiency and effectiveness of the management of the agency.
- 8. Report any possible abuses, illegal actions, errors, omissions and conflicts of interest of which the Division becomes aware during the performance of an audit.
- 9. Adopt the standards of the Institute of Internal Auditors for conducting and reporting on internal audits.
- 10. Consult with the Legislative Auditor concerning the plan for auditing and the scope of audits to avoid duplication of effort and undue disruption of the functions of agencies that are audited pursuant to subsection 5.
 - 11. Appoint a Manager of Internal Controls.





Sec. 23. Section 4 of chapter 410, Statutes of Nevada 2007, at page 1793, is hereby amended to read as follows:

- Sec. 4. 1. The Nevada Institutional Review Board shall not, during the period beginning upon passage and approval of this act and ending on [July 1,] June 30, 2009, meet or otherwise exercise any of the powers or duties authorized pursuant to chapter 630A of NRS, except:
 - (a) As otherwise provided in subsection 2; or
- (b) As necessary to carry out the provisions of subsections 3 to 8, inclusive.
- 2. If the Legislative Commission determines that it is in the best interests of this State, the Legislative Commission may, during the period described in subsection 1, authorize the Nevada Institutional Review Board to contract with a private company to conduct studies or other work related to nonembryonic stem cells in bioregenerative medical technology.
- 3. The Nevada Institutional Review Board shall, not later than [July 1,] June 30, 2009:
- (a) Return the unexpended portion of any grant, gift, appropriation or donation that was received by the Board subject to a condition that requires its return if it cannot be used to carry out the duties of the Board;
- (b) Transfer any money that remains in any account maintained by the Nevada Institutional Review Board after complying with paragraph (a) to the Board of Homeopathic Medical Examiners; and
- (c) Transfer all books, records, minutes, documents and other property of the Nevada Institutional Review Board to the [Board of Homeopathic Medical Examiners.] Office of the Governor.
- 4. Any regulations adopted by the Nevada Institutional Review Board, or by the Board of Homeopathic Medical Examiners concerning the Nevada Institutional Review Board, are void on [July 1,] June 30, 2009. The Legislative Counsel shall remove those regulations from the Nevada Administrative Code as soon as practicable after [July 1,] June 30, 2009.
- 5. Any contract entered into by the Nevada Institutional Review Board, or by the Board of Homeopathic Medical Examiners concerning the Nevada Institutional Review Board, including, without limitation, a contract for employment and a contract for the services of a person pursuant to NRS 284.013, that is not fully performed on [July 1,] June 30, 2009, is void.





- 6. If the Board of Homeopathic Medical Examiners has created a nonprofit organization pursuant to NRS 630A.875, including, without limitation, the NIRB Medical Foundation, the Board of Homeopathic Medical Examiners shall, not later than [July 1,] June 30, 2009, dissolve the nonprofit organization.
- 7. The Nevada Institutional Review Board shall cooperate with the Board of Homeopathic Medical Examiners to ensure that the provisions of this act are carried out in an orderly manner.
- 8. The terms of the members of the Nevada Institutional Review Board expire on [July 1,] June 30, 2009.

Sec. 24. As soon as practicable:

- 1. After July 1, 2009, each appointing authority responsible for the appointment of members to the Institutional Review Board of Nevada created pursuant to section 9 of this act shall make its initial appointments.
- 2. After the members of the Institutional Review Board of Nevada have been appointed pursuant to subsection 1, the Office of the Governor shall transfer all books, records, minutes, documents and other property received from the Nevada Institutional Review Board to the Institutional Review Board of Nevada.
- **Sec. 25.** 1. This section and section 23 of this act become effective upon passage and approval.
- 2. Sections 1 to 22, inclusive, and 24 of this act become effective on July 1, 2009.





