SENATE BILL NO. 371–SENATOR SCHNEIDER

MARCH 16, 2001

Referred to Committee on Human Resources and Facilities

SUMMARY—Creates state committee on pain management issues. (BDR 40-1242)

FISCAL NOTE: Effect on Local Government: No.
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; creating a state committee on pain management issues; prescribing the membership and duties of the committee; authorizing persons to apply to the committee for approval of research programs for pain management; providing immunity from civil and criminal liability for the possession and delivery of controlled substances and certain drugs under certain circumstances; making an appropriation; and providing other matters properly relating thereto.

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

Section 1. Title 40 of NRS is hereby amended by adding thereto a new chapter to consist of the provisions set forth as sections 2 to 9, inclusive, of this act.

Sec. 2. ***As used in this chapter, unless the context otherwise requires, "state committee" means the state committee on pain management issues.***

Sec. 3. ***1. The state committee on pain management issues is hereby created. The state committee consists of seven members appointed by the governor as follows:***

(a) Three members who are physicians licensed pursuant to chapter 630 or 633 of NRS, as applicable, and who:

(1) Are actively engaged in the practice of medicine or osteopathy in this state;

(2) Have at least 5 years of experience in the practice of medicine or osteopathy in this state; and

(3) Represent the specialties of practice that treat a chronic or debilitating medical condition.

(b) Two members who are pharmacists registered pursuant to chapter 639 of NRS and who:

(1) Are actively engaged in the practice of pharmacy in this state; and

(2) Have at least 5 years of experience in the practice of pharmacy in this state.

(c) Two members who represent the general public and who are not related by consanguinity or affinity within the third degree to a physician or pharmacist who practices in this state.

The governor shall not appoint to serve on the state committee any person who has a direct or indirect interest in a research program for pain management.

2. To the extent practicable, a person who is appointed to serve on the state committee pursuant to subsection 1 must possess knowledge of and experience in reading and interpreting research protocols and data or possess specific knowledge of the research regarding pain management.

3. Within 30 days after his appointment, a member of the state committee shall take and subscribe to an oath to carry out his duties pursuant to this chapter in a faithful and impartial manner.

4. The members of the state committee shall select a chairman and vice chairman from among their membership.

5. After the initial terms, each member of the state committee serves a term of 3 years. A member of the state committee may not serve for more than three consecutive terms. If a vacancy occurs on the state committee, the vacancy must be filled in the same manner as the original appointment for the remainder of the unexpired term.

6. Each member of the state committee is entitled to receive for each day or portion of a day that he attends a meeting of the state committee or is otherwise engaged in the business of the state committee:

(a) A salary of $80; and

(b) The per diem allowance and travel expenses provided for state officers and employees generally.

7. The health division of the department of human resources shall provide administrative support to the state committee.

8. Each member of the state committee serves at the pleasure of the governor.

Sec. 4. *1. The state committee shall promote appropriate protocols for pain management within this state and clinical trials of drugs. In carrying out such duties, the state committee shall meet at least quarterly, or at the call of the chairman, and shall:*

(a) Work cooperatively with the state board of pharmacy, the board of medical examiners, the state board of osteopathic medicine and the University and Community College System of Nevada to establish educational programs for health professionals to disseminate information concerning the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain adopted in May 1998 by the Federation of State Medical Boards of the United States, Inc.

(b) Work cooperatively with the University of Nevada School of Medicine and apply for available federal grants to conduct clinical trials of drugs and other research relating to pain management issues.

(c) Develop and carry out incentive programs to encourage physicians and osteopathic physicians to locate in Nevada for the purpose of

conducting clinical trials of drugs that are appropriate to pain management.

2. The state committee shall hold two meetings each year at the call of the chairman to review applications submitted to the state committee for the approval of a research program for pain management. Within the limits of money available to the state committee, the state committee may hold additional meetings at the call of the chairman.

3. Four members of the state committee constitute a quorum for the transaction of business. A majority vote of the members present is required to take action with respect to any matter.

Sec. 5. *1. A person may submit an application to the state committee for the approval of a research program for pain management. An application must be submitted on a form provided by the state committee.*

2. The state committee shall review each application that it receives to determine whether:

(a) The primary purpose of the proposed research program is to treat or alleviate a chronic or debilitating medical condition; and

(b) The proposed research program:

(1) Complies with all federal laws and guidelines for such research;

(2) Incorporates adequate safeguards to ensure that the distribution of controlled substances and other drugs for purposes of the program is made only to those persons who are participating in the program and is not diverted for unlawful or unauthorized use;

(3) Adequately protects the confidentiality of those persons who participate in the program, and provides access to the identity of those persons by authorized employees of state and local law enforcement agencies only as is necessary to verify the status of a person as a participant in an approved research program;

(4) Incorporates adequate protections for the health and safety of the persons who participate in the program; and

(5) Is likely to produce results that are scientifically and medically valid.

3. The state committee shall make a determination on an application within a reasonable period after receipt of the application. A determination of the state committee is final and not subject to appeal. The determination of the state committee must be based upon:

(a) The review of the application pursuant to subsection 2;

(b) Materials, if any, accompanying the application;

(c) Personal interviews conducted by the state committee, if any, of the proponents of the application; and

(d) Any other information or material relevant to the proposed research program.

4. If the state committee approves a research program, the state committee shall prepare and provide to the applicant a written statement indicating its approval of the research program in a format that may be submitted by the applicant to the Federal Government for registration pursuant to 21 U.S.C. § 823 in connection with the research program. A person shall not conduct a research program for pain management until

he has obtained all necessary approvals from the Federal Government pursuant to 21 U.S.C. § 823, regardless of whether the state committee has approved the research program.

5. To the extent that money is made available by legislative appropriation or otherwise, the state committee may distribute money to successful applicants who are registered pursuant to 21 U.S.C. § 823 to conduct the research program. The state committee may determine the amount of money so distributed and any conditions for receipt of the money.

6. If the Federal Government suspends or revokes the registration of a person to conduct a research program, the approval of the research program by the state committee shall be deemed revoked.

Sec. 6. *If the state committee or a member of the state committee, acting pursuant to this chapter, initiates or assists in any proceeding concerning an application for approval of a research program, the state committee and its members are immune from any civil action for such initiation or assistance or any consequential damages, if the state committee and its members acted without malicious intent.*

Sec. 7. *Except as otherwise provided in section 8 of this act, if a person has obtained the approval of the state committee for a research program for pain management and that person is registered to conduct the research program by the Federal Government pursuant to 21 U.S.C. § 823, the:*

1. Person who conducts or operates the program and any person working under his immediate direction, supervision or instruction for the program;

2. Physicians and pharmacists assisting with the program and those persons working under their immediate direction, supervision or instruction for the program; and

3. Persons who participate in the program,

are exempt from criminal prosecution in this state and are immune from civil and criminal liability in this state for the possession or delivery of any controlled substance, any dangerous drug as defined in NRS 454.201, or any other drug specific to the approved research program.

Sec. 8. *The provisions of this chapter do not:*

1. Authorize the possession or delivery of any controlled substance, any dangerous drug as defined in NRS 454.201 or any other drug for purposes other than those related to a research program that has been approved by the state committee and authorized by federal law;

2. Require an insurer, organization for managed care or any person or entity who provides coverage for a medical or health care service to pay for or reimburse a person participating in an approved research program for pain management for costs associated with that research;

3. Protect a person against prosecution or civil liability for any act involving the possession or delivery of a controlled substance, any dangerous drug as defined in NRS 454.201 or any other drug in a manner not authorized pursuant to this chapter; or

4. Require an employer or any operator of a place of public accommodation to authorize research relating to pain management on its premises or otherwise make accommodations for such research.

Sec. 9. ***1. The state committee shall adopt regulations prescribing the:***

(a) Process for submission of an application by a person for the approval of a research program pursuant to section 5 of this act;

(b) Criteria and type of investigation that will be applied by the state committee in determining whether to approve an application;

(c) Conditions, if any, under which the state committee may allow a person to resubmit an application that has been denied by the state committee; and

(d) Except as otherwise provided in subsection 6 of section 5 of this act, conditions under which the state committee may revoke its approval of a research program.

2. The state committee may adopt such regulations:

(a) As the state committee determines are necessary to carry out its duties pursuant to this chapter.

(b) Not inconsistent with the constitution or laws of the United States, or of this state, as the state committee determines are necessary to protect the public with regard to research relating to pain management.

Sec. 10. Chapter 453 of NRS is hereby amended by adding thereto a new section to read as follows:

The provisions of this chapter do not apply to the extent that they are inconsistent with the provisions of sections 2 to 9, inclusive, of this act.

Sec. 11. Chapter 630 of NRS is hereby amended by adding thereto a new section to read as follows:

The board shall adopt regulations governing the use of controlled substances for the treatment of pain. The regulations must be substantially similar to the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain adopted in May 1998 by the Federation of State Medical Boards of the United States, Inc., to the extent that the board determines that the model guidelines are appropriate for use in this state.

Sec. 12. NRS 630.3066 is hereby amended to read as follows:

630.3066 A physician is not subject to disciplinary action solely for ~~[prescribing]~~ ***:***

1. Prescribing or administering to a patient under his care:

~~[1.]~~ ***(a)*** Amygdalin (laetrile), if the patient has consented in writing to the use of the substance.

~~[2.]~~ ***(b)*** Procaine hydrochloride with preservatives and stabilizers (Gerovital H3).

~~[3.]~~ ***(c)*** A controlled substance which is listed in schedule II, III, IV or V by the state board of pharmacy pursuant to NRS 453.146, if the controlled substance is lawfully prescribed or administered for the treatment of intractable pain in accordance with accepted standards for the practice of medicine.

2. Conducting or assisting with a research program that has been approved by the state committee on pain management issues pursuant to

section 5 of this act if the person who conducts the research program is registered pursuant to 21 U.S.C. § 823 and conducts the research in accordance with state and federal law.

Sec. 13. Chapter 633 of NRS is hereby amended by adding thereto a new section to read as follows:

The board shall adopt regulations governing the use of controlled substances for the treatment of pain. The regulations must be substantially similar to the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain adopted in May 1998 by the Federation of State Medical Boards of the United States, Inc., to the extent that the board determines that the model guidelines are appropriate for use in this state.

Sec. 14. NRS 633.521 is hereby amended to read as follows:

633.521 An osteopathic physician is not subject to disciplinary action solely for ~~[prescribing]~~ ***:***

1. Prescribing or administering to a patient under his care:

~~[1.]~~ ***(a)*** Amygdalin (laetrile), if the patient has consented to the use of the substance.

~~[2.]~~ ***(b)*** Procaine hydrochloride with preservatives and stabilizers (Gerovital H3).

~~[3.]~~ ***(c)*** A controlled substance which is listed in schedule II, III, IV or V by the state board of pharmacy pursuant to NRS 453.146, if the controlled substance is lawfully prescribed or administered for the treatment of intractable pain in accordance with accepted standards for the practice of osteopathic medicine.

2. Conducting or assisting with a research program that has been approved by the state committee on pain management issues pursuant to section 5 of this act if the person who conducts the research program is registered pursuant to 21 U.S.C. § 823 and conducts the research in accordance with state and federal law.

Sec. 15. NRS 639.2176 is hereby amended to read as follows:

639.2176 The board shall adopt regulations ~~[necessary]~~ ***:***

1. Necessary to carry out the purposes of NRS 639.2171 to 639.2176, inclusive, which must include the methods of determining accredited programs, the number of hours of continuing professional education necessary to constitute a continuing education unit, the number of units required of each pharmacist during the period for which a certificate is issued and such other regulations consistent with NRS 639.2171 to 639.2176, inclusive, as the board may determine to be necessary.

2. Requiring each registered pharmacist to be knowledgeable concerning the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain adopted in May 1998 by the Federation of State Medical Boards of the United States, Inc., to the extent that the board determines that the model guidelines are appropriate for use in this state.

Sec. 16. 1. There is hereby appropriated from the state general fund to the health division of the department of human resources the sum of $5,000 for the payment of:

(a) The salaries, per diem allowances and travel expenses of the members of the state committee on pain management issues created by section 3 of this act; and

(b) Incidental expenses of the health division incurred in providing administrative assistance to the state committee on pain management issues.

2. Any remaining balance of the appropriation made by subsection 1 must not be committed for expenditure after June 30, 2003, and reverts to the state general fund as soon as all payments of money committed have been made.

Sec. 17. 1. On or before October 1, 2001, the governor shall appoint the following members to the state committee on pain management issues to terms expiring September 30, 2003:

(a) Two members pursuant to paragraph (a) of subsection 1 of section 3 of this act;

(b) One member pursuant to paragraph (b) of subsection 1 of section 3 of this act; and

(c) One member pursuant to paragraph (c) of subsection 1 of section 3 of this act.

2. On or before October 1, 2001, the governor shall appoint the following members to the state committee on pain management issues to terms expiring on September 30, 2004:

(a) One member pursuant to paragraph (a) of subsection 1 of section 3 of this act;

(b) One member pursuant to paragraph (b) of subsection 1 of section 3 of this act; and

(c) One member pursuant to paragraph (c) of subsection 1 of section 3 of this act.

Sec. 18. The state committee on pain management issues shall:

1. On or before July 1, 2002, submit a report of its progress to the director of the legislative counsel bureau for transmittal to the legislative committee on health care; and

2. On or before January 1, 2003, submit a full report of its activities and any findings or recommendations to the director of the legislative counsel bureau for transmittal to the 72nd session of the Nevada legislature.

Sec. 19. This act becomes effective upon passage and approval for the purpose of appointing the members of the state committee on pain management issues and on October 1, 2001, for all other purposes.

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