

BUREAU OF NATUROPATHIC MEDICINE P.O. BOX 980490, WEST SACRAMENTO, CA 95798-0490 400 R STREET, SUITE 3030, SACRAMENTO, CA 95814-6200 (916) 445-8692 / (916) 322-1651 (FAX) WEBSITE: www.naturopathic.ca.gov



NATUROPATHIC FORMULARY ADVISORY COMMITTEE

Meeting Minutes June 26, 2005

Meeting Site:
The Khalsa Medical Clinic
436 North Bedford Drive, Suite 308
Beverly Hills, CA 90210

<u>Teleconference Site 1:</u> 29 Ulana Street Makawao, HI 96768

<u>Teleconference Site 2:</u> 2140 E. Broadway Road Tempe, AZ 85282

COMMITTEE MEMBERS

Mary Hardy, Medical Doctor

Trevor Holly Cates, Naturopathic Doctor

Soram Khalsa, Medical Doctor Cynthia Watson, Medical Doctor

Peter Wannigman, Naturopathic Doctor Michael Traub, Naturopathic Doctor Paul Mittman, Naturopathic Doctor

COMMITTEE MEMBERS

ABSENT:

PRESENT:

None

STAFF PRESENT: Kathy McKeever, Bureau Chief

Joanne Davis. Assistant to Bureau Chief

I. Welcome and Call to Order

Kathy McKeever welcomed the members and the public to the meeting and called the meeting to order at 5:20 p.m, pacific daylight time. Roll was taken and a quorum was declared. Members and staff introduced themselves.

II. Bureau Chief's Update

Kathy asked the members to focus on setting timelines to help accomplish the legislatively mandated recommendations.

Kathy updated the committee members on a question that the Naturopathic Medicine Advisory Council had regarding medical malpractice insurance of physicians while supervising the naturopathic doctors. Kathy contacted a risk management specialist at NorCal Mutual Insurance Company to inquire about malpractice insurance rates for physicians supervising naturopathic doctors. The premium for a supervising physician would be about the same as a

physician who supervises a nurse practitioner or physician's assistant; however, the liability will be shared between the supervising physician and the naturopathic doctor.

The Committee asked Kathy to also inquire with two other companies -- SCPIE and Doctor's Company. Dr. Hardy indicated she would also contact SCPIE.

Questions to address:

Is there a difference in the law between a dependent practitioner, who must have a medical doctor countersign orders, and an independent practitioner, who has independent prescribing authority?

What is supervision?

What is the legal liability for medical doctor (MD) and naturopathic doctor (ND?

What is the cost for MD to supervise a ND vs not supervising?

The Committee discussed the fact that other states licensing naturopathic doctors do not require a naturopathic doctor to have a supervising physician and that could be part of the recommendations to the legislature.

Dr. Wannigman, ND, updated the members on how the supervising piece fell into the statute (SB 907). California Medical Association (CMA) was going to oppose the bill (SB 907) completely because they did not fully understand the range of education and training that naturopathic doctors receive in the naturopathic medical schools, and CMA was unclear on what categories of medications the NDs were going to prescribe. CMA supported the bill only if the naturopathic doctors would be supervised by a medical doctor if they were going to prescribe drugs and a Formulary committee was form to look into these areas of concerns and provide recommendations back to the legislature.

Dr. Mittman, ND, indicated that Arizona naturopathic doctors are allowed to prescribe legend drugs in section 321901 (of the Arizona Pharmacy Board), but does not include intravenous administration of the legend drugs, except for vitamins, chelation therapy and drugs used in emergency resuscitation stabilization. They cannot prescribe federally controlled substances in schedules I and II, except morphine. They cannot prescribe cancer chemotherapeutices and antipsychotics.

Dr. Traub, ND, indicated that Hawaii naturopathic doctors are more restricted on what they can prescribe than Arizona and other states. Hawaii NDs cannot prescribe chelation.

Dr. Cates, ND, provided committee members information on Oregon, Utah, and Washington naturopathic doctors rules.

III. Election of Chair and Vice-Chair

It was moved and seconded (Khalsa/Cates) to elect Dr. Wannigman, ND, as the Chair of the Formulary Advisory Committee. Roll was called and the move was carried unanimously.

It was moved and seconded (Cates/Hardy) to elect Dr. Khalsa as the Vice-Chair of the Formulary Advisory Committee. Roll was called and the move was carried unanimously.

IV. Adoption of the Committee's Procedural Rules

It was moved and seconded (Hardy/Khalsa) to adopt the Robert's Rules and Orders as the Committee's procedural rules. Roll was called and the move was carried unanimously.

V. Review of Naturopathic Doctor's Act and Regulations

The members reviewed and discussed sections: 3627, 3640.5, 3640.7, and 3640(c)(1), 3640(d), and 3640(e) of the Business and Professions Code; and Section 4236 of California regulations.

Members discussed that there are things that would fall under the category of foods, extracts, amino acids, minerals, and things that because of their route of administration would become a drug, such as B-12. An oral form of B-12 is a dietary supplement, but if it is put into an injectable form, then it becomes a drug. Can NDs independently prescribe the injectable B-12 or does it require a supervising protocol?

Members discussed section 3640(c)(1) of the Business and Professions Code and whether or not it would be an extension in scope of practice to allow naturopathic doctors the abilities to use the routes of administration for such things as vitamins, amino acids, nutriceuticals, minerals, etc. Members indicated that the CMA might see this as an expansion of scope. Committee members agreed they would need more information on what is taught in the naturopathic medical schools in regards to IV therapeutics. Information is be submitted to Dr. Hardy and Dr. Watson.

The Committee discussed chelation and whether or not it could be part of scope of practice. Dr. Mittman, ND, indicated that Arizona's law (for NDs) on chelation is used only for heavy metal poison or heavy metal toxicity. The law does not intend for NDs to be doing chelation therapy the way the physicians are trained to use chelation therapy for cardiovascular disease. A ND to be using EDTA should be able to demonstrate that the patient has heavy metal poisoning. Dr. Mittman, ND, further clarified that it is his understanding that if NDs perform chelation therapy for cardiovasular disease it would have to be part of an experimental procedure that would require IRB approval.

The committee agreed that chelation therapy or EDTA is not currently in the California Naturopathic Doctors Act. The committee members were not oppose for NDs to perform

chelation therapy if it is used for heavy metal detoxification and not used to treat heart disease; however, this is not in the Act and would be an expansion of scope of practice.

Committee members discussed and felt the Act was unclear on whether or not NDs can give intravenously botanical medicines and homeopathic medicines. Members discussed requiring a certification course.

Kathy explained if time permits the formulary recommendations of this committee should be presented to the full Advisory Council. The recommendations are due to the Legislature July 1, 2006; however, the recommendations need to be completed by November 2005 for department and agency review.

VI. Overview of Arizona's Formulary Requirements

Dr. Mittman, ND, reread the Arizona's law – intravenous administration of legend drugs is not allowed. The Arizona law states that a drug has the same meaning prescribed in Section 321901, Arizona Pharmacy Board statute, but does not include IV administration of legend drugs except for vitamins, chelation therapy, and drugs used in emergency resuscitation and stabilization.

The Committee discussed the variations in the curriculum from the different naturopathic medical schools. Bastyr in Washington will soon be adding IV therapy to their curriculum. Oregon and Arizona both have IV therapy in their curriculum. Bridgeport offers IV therapy as an elective.

Dr. Mittman, ND, faxed a one page sheet (titled Senate Amendments to H.B. 2028, numbered page 11 at the bottom) and was distributed to the committee members. Line 14 J. indicates a licensed naturopathic doctor who elects to prescribe drugs shall complete and pass a Board approved course and examination as a condition of being able to prescribe drugs.

The Committee discussed pharmacology hours of those NDs that graduated from school 5, 10, 15, or 20 years, which may necessitate them to take specific pharmacology course(s) before furnishing or prescribing drugs. California requires 48 hours of pharmacology and 20 hours as part of continuing education (CE) every two years. Arizona requires 60 hours pharmacology and 10 hours annually. Oregon requires 10 hours of CE in pharmacy annually.

Dr. Mittman, ND, explained how Arizona set their pharmacology requirement. They worked with two other medical schools, the University of Arizona School of Medicine and Midwestern Osteopathic School, as well as the Arizona Medical Association, Pharmacy Association. Southwest College revised their curriculum so that they would have the same number of hours as those two schools, including the same number of continuing medical education hours each year. Southwest College's pharmacy hours are consistent with the requirements of other physicians training.

VII. Review of Other State's Naturopathic Doctors Prescribing Requirements

Dr. Hardy requested a copy of the pharmacology syllabi from each of the various naturopathic medical schools.

Dr. Hardy requested information, preferably laid out in a table format, on what the prescribing rights are from the other states, as well as their what their continuing education requirements. During this discussion, Dr. Mittman, ND, emailed a chart to Dr. Khalsa that list all 50 states. It will be emailed to Joanne Davis to format to reduced to only the states that license NDs. Dr. Traub, ND, will inquire with CNDA to see if they have this type of information; if so, he will send to Joanne for distribution to committee members.

Dr. Mittman, ND, indicated he would send the members a password so they could look at the actual classes at Southwest. The materials are available on-line, but committee members will need a password to view the syllabi on-line.

The pharmacology of other schools are 72 hours at National, 72 hours at Bridgeport, and 55 hours at Bastyr. Southwest has 120 hours of pharmacology.

Dr. Mittman, ND, indicated that graduates from an another school would have to take a 60-hour pharmacology review course to have prescribing privileges. The course is taught over a two-year period. The Board is working on ways to make it available as an on-line course. Dr. Mittman, ND, will email the committee members the curriculum for this course.

Dr. Traub, ND, will inquire with NCMIC for data on malpractice claim incidents of naturopathic doctors.

Dr. Mittman, ND, will email Joanne Davis an internet site called Jury Verdicts to get information on civil verdicts and settlements in Washington, Idaho, Oregon, and Alaska.

Dr. Khalsa, Dr. Hardy, and Dr. Watson will call their respective malpractice companies to inquire what the premiums would be with and without a nurse practitioner.

VIII. Discussion of Section 3627 of the Business and Professions Code

The Committee discussed recommendations to include in the Report to the Legislature:

- IV and IM with vitamins, minerals, nutrients, and amino acids.
- Curriculum and course requirements for IV and IM for vitamins, minerals, and amino acids.
- Current pharmacology training of the naturopathic medical schools.
- Necessary level of training for a ND to prescribe legend drugs without supervision or protocol.

IX. Dates for Future Meetings

The next couple of meetings will be planned for July 31, 2005 beginning at 3:00 p.m. and August 28, 2005 beginning at 10:00 a.m.

X. Public Comment

Chairman Wannigman opened the floor for public comment.

A public member commented that public protection should be number one and public assurance that safety techniques and technical knowledge are being used the same across the board. She wanted clarification on the make-up and purpose of this committee.

Another public member asked questions pertaining to naturopathic residency in California.

XI. Adjournment

The meeting was adjourned at 7:50 p.m., pacific daylight time.