State of California Department of Consumer Affairs

BUREAU OF NATUROPATHIC MEDICINE
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NATUROPATHIC FORMULARY ADVISORY COMMITTEE

Meeting Minutes

October 23, 2005

Meeting Site:	Teleconference Site:	Public Location Site:
The Khalsa Medical Clinic	Michael Traub, ND	Trevor Holly Cates, ND
436 North Bedford Drive, Suite 308	73-1138 Oluolu Street	34 E. Sola Street, Room 5
Beverly Hills, CA 90210	Kailua Kona, HI 94740	Santa Barbara, CA 93101

COMMITTEE MEMBERS PRESENT: Peter Wannigman, Naturopathic Doctor (Chairman)
Soram Khalsa, Medical Doctor (Vice-Chairman)
Mary Hardy, Medical Doctor
Trevor Holly Cates, Naturopathic Doctor
Michael Traub, Naturopathic Doctor
Paul Mittman, Naturopathic Doctor
Larry Woodhouse, Pharmacist

COMMITTEE MEMBERS ABSENT: Cynthia Watson, Medical Doctor
Arthur Presser, Pharmacist

STAFF PRESENT: Joanne Davis
Linda Brown

I. Call to Order and Roll Call

Chairman Wannigman called the meeting to order at 10:00 a.m. (pacific daylight time). Roll call was taken and a quorum declared.

II. Approval of the September 25, 2005 Committee Meetings Minutes

This action item was tabled to the next Committee meeting.

III. Chairperson's Report

Chairman Wannigman announced the Governor signed AB 302 and a copy was provided in the meeting packets. Chairman Wannigman read the amended Section of 3640(c)(1).

IV. Review of DCA's Legal Opinions: Administration of IV Therapy by NDs, Anabolic Steroids Exempt from Schedule III Controlled Substances, and Naturopathic Doctors: Prescribing

The three legal opinions were provided in the members' meeting packets. Members briefly reviewed and discussed each legal opinion. The Bureau advised the members that legal counsel was not able to attend today's meeting, but will be available at the next meeting to answer questions.

The Committee discussed the impact of AB 302, specifically the amended Section 3640(c)(1) which added the following words…"consistent with the routes of administration identified in subdivision (d)." Members wanted to know whether this new language granted NDs to independently perform routes of administration listed in subdivision (d) (which includes intravenous and intramuscular) for substances listed in Section 3640 (c)(1) without the MD oversight supervision. The Bureau indicated that DCA legal counsel is reviewing the signed bill in its entirety and will be available at the next Committee meeting to provide a legal consultation on AB 302 and legal interpretation to the amended Section 3640 (c)(1).

Chair Wannigman indicated that the Committee is not attempting to control the routes of administration that would be subcutaneous, sub dermal, and intramuscular. The Committee is here to discuss IV.

V. Update on Medical Malpractice Under Physician Supervision

Joanne Davis reported on the following:

- SCIPE would not cover NDs. RNs, and PAs can be endorsed on the MDs coverage, but SCIPE would not endorse NDs. However, SCIPE would cover MDs supervising NDs if the NDs are considered staff and that rate would vary depending on the county. SCIPE suggested we also contact Affinity Services Group.

- The Doctor's Company indicated that there would be a 10% surcharge for MDs who supervise NDs.

  Follow-up questions to ask the malpractice companies:

  Will SCIPE allow NDs to be offsite from supervising MD?
  Does SCIPE charge a surcharge? If so, what is the rate?
  Does the ND have to have the same insurance coverage as the MD?
  Does the Doctor's Company allow NDs to be offsite from MD?

Dr. Hardy and Dr. Khalsa will forward Joanne a list of follow-up questions for the insurance companies.

Dr. Hardy requested for the Bureau to add this topic on medical malpractice to the next Naturopathic Advisory Council agenda as it covers more than just prescribing concerns.

VI. Discussion on IV Formulary

This discussion was combined with *VII. Continue Discussion on IV Course Requirements.*

VII. Continue Discussion on IV Course Requirements

Members' meeting packet included a Blueprint provided by Virginia Osborne called Fundamentals of IV Micronutrient Therapy. After some discussions, members agreed for the Blueprint to be revised as follows:

- 25 direct contact hours of training of which no less will be 14 hours of practicum (lunch and breaks are not to be counted as part of the direct hours).

- Add jurisprudence questions.

- IV contacts include a minimum of 20, of which 10 are physical patient contacts.

- Add language in the practicum section that includes demonstration of identifying and proper intravenous access for utilizing in a sterile manner, preexisting deep venous access, choosing appropriate protocol, doing the correct calculation, managing common complications, and demonstrating knowledge of emergency techniques, including when to seek additional medical assistance.

- Add language that if NDs chose to do pic lines that they must obtain additional training on their own before using and managing pic lines. In addition, include language on coordination and management of shared lines.

- Add language to the pharmacology portion on appropriate reporting and procedures for serious adverse events, including FDA and Med Watch online reporting.

- IV EDTA of chelation is to be used only for heavy metal detoxification, unless under the auspices of IRB approved research protocol.

In addition, the Committee proposed the following requirements:

- The certification examination will be required for anyone within the State of California and will allow for reciprocity of this Blueprint from other states. Reciprocity is appropriate, but all licensees must take a certification examination.

- Require re-certification every five years to be deferred to the Bureau for re-certification development by the Advisory Council and suggest 8 hours of didactic every 5 years.

The Committee discussed having a chelation blueprint. The chelation blueprint would require a minimum of 12 hours of direct contact learning. For the December 11th meeting Ms. Osborne will present a revised Oregon Blueprint for chelation. Prior to the meeting, Ms. Osborne will provide the blueprint to the Bureau for inclusion in the meeting packets.

At the next Committee meeting, members will review and vote on the revised IV Blueprint and Chelation Blueprint.

VIII. Continue Discussion on Formulary

Chairman Wannigman presented a proposal for IV Formulary, which included the following.

To have Categories:
1. Botanicals
2. Chelating Agents
3. Specialty Products
4. Biologicals – using a definition similar to New Mexico's definition of biologicals, which reads *"Natural substances exist in nature or are formed by natural forces, processes or entities including their constituents, preparations, concentrates, refinements, isolates, extracts, derivatives, byproducts, ligands and metabolites, and the synthetic chemical surrogates, isomers and analogues of these. A natural substance may be the crude substance or a constituent derived from the crude substance, or a synthesized chemical surrogate, isomer or analogue of the constituent. Natural substances may be classified as drugs, dangerous drugs or controlled substances as these are defined in the New Mexico Drug Device and Cosmetic Act or the Controlled Substances Act."*

Chairman Wannigman suggested for adoption of new things to be inclusive in these categories that would not require regulations, but rather an approval from the Advisory Council on, perhaps, an annual basis.

Members had concerns over the biologicals definition as being too broad, specifically the usage of atoms, molecules, and elements. Members felt an inclusionary list would be fine and the broad definition would not be a problem. If it's an exclusionary list or anything goes, then the broad definition becomes a big problem. Members also discussed the compounding for parenteral use and that the products must be commercially available and must meet FDA standards. Dr. Hardy will forward a copy of the Proposed Rule for the Quality Manufacturing of Dietary Supplements, which has been composed by the FDA over a year ago, to members for review.

Language for the inclusionary list should state something to the effect that anything that is used for intravenous use by ND must be commercially available and meet certain standards of quality. Larry Woodhouse suggested the Committee review USP Chapter 797 Sterile Compound, which is considered the standard.

After some discussion, members agreed that Botanicals would fall under the biologicals category. Members also discussed what herbs are currently created by compounding pharmacies? Members briefly discussed herb preparations, including echinacea, Silymarin, and glycyrrhizic acid. Virginia Osborne indicated she would research the preparation of these herbs. Members agreed that Silymarin and glycerin would fall under biologicals. Dr. Hardy will forward the website and number for the FDA Watch to Dr. Osborne to include in the class course.

Members discussed homeopathy medicines and remedies. Because the safety margins of homeopathy medicines are so broad, members felt there should not be a lot of limitations on homeopathic remedies, under the Specialty Product category. Homeopathics will be classified as a general group.

Members asked for a legal opinion on the definition of homeopathic medicine and proposed using the following definition: *"all drugs that appear in homeopathic pharmacopeias of the US and any other substance prepared in homeopathic potency that has indications for homeopathic use and has appeared in professional literature."* Chairman Wannigman will send the proposed definition to the Bureau for the legal opinion request.

Chairman Wannigman indicated he would like to see for the next meeting, the members' vote on the items to include in the categories.

Chairman Wannigman entertained a discussion on procaine and NDs use of it would be for prolotherapy. Members agreed that in order for NDs to do prolotherapy and use procaine it would require legislation and not a regulatory action. This discussion was tabled for next Committee meeting.

IX. Committee Meeting Calendar

Joanne distributed a revised 2006 Council meeting calendar. Council meetings are scheduled to be held on the following Sundays: January 29, May 21, and September 17 all beginning at 11:00 a.m.

Members agreed the November 20, 2005 Formulary Committee meeting would be canceled and selected the following meeting dates: December 11, 2005 and January 15, 2006 beginning at 10:00 a.m.

The main business of the December 11th Formulary meeting will be to finalize the document for the Council meeting on January 29th.

X. Public Comment

Joanne Davis announced her official last day with the Bureau is November 18, 2005. Until a replacement is named, Terri Ciau and Linda Brown will take over the Bureau's workload, including staffing and coordinating the Committee meetings.

XI. Adjournment

The meeting was adjourned at 1:40p.m.