State of California Department of Consumer Affairs

BUREAU OF NATUROPATHIC MEDICINE
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NATUROPATHIC MEDICINE ADVISORY COUNCIL

Meeting Minutes
June 6, 2005

Meeting Site:
Department of Consumer Affairs
400 R Street, Third Floor, Suite 3020
"Mimi Modisette" Conference Room
Sacramento, CA 95814

Teleconference Site
LSU Health Sciences Center
433 Bolivar Street, Room 827
New Orleans, LA 70112

COUNCIL MEMBERS PRESENT:
Carl Hangee-Bauer, Chair
Cynthia Watson
Soram Khalsa
Trevor Cates
Mary Hardy
David Field
Daisy Ma

COUNCIL MEMBERS ABSENT:
Alexandra Cock, Vice Chair

STAFF PRESENT:
Kathy McKeever, Bureau Chief
Norine Marks, Legal Counsel
Joanne Davis, Assistant to Bureau Chief

I. Welcome and Call to Order

The meeting was called to order at 10:10 a.m. Roll call was taken and a quorum was declared.

II. Approval of the March 14, 2005 Meeting Minutes

Members reviewed and requested to amend the minutes on page 3, first bullet, change "cardiactic" to "cardiac". It was moved and seconded (Field/Khalsa) to approve the minutes as amended. Roll call vote was taken and the move was carried unanimously.

Chairman Hangee-Bauer indicated that agenda item *VII. Bureau Chief's Update* would be heard first to accommodate the guest speaker from the federal Drug and Enforcement Administration (DEA).

VII. Bureau Chief's Update

John Steen, representative from DEA in San Francisco spoke to the Council regarding mid-level practitioners' registration requirements with DEA. DEA recently approved California naturopathic doctors to prescribe only schedules III-V. DEA uses various terms such as handle, dispense, and prescribe of controlled substances. The state uses the term furnish to mean prescribe. However, DEA uses the term furnish to mean to have the drug and administer it to a patient. Naturopathic doctors who have been issued a furnishing number through the Bureau may apply to their regional DEA office for a DEA number by completing a Registration Application DEA Form 224, which is included in the members' meeting packets. The form is available on the DEA's website at <www. deadiversion.usdoj.gov>. Mr. Steen expressed that when completing the DEA Form 224, naturopathic doctors are to check the MLP in Box 1, to fill in their NDF number as their State License No. in Box 4, do not check state Controlled Substance No. as it does not apply for California. The application fee for DEA registration is $390 for three years and can be paid online by credit card.

California is only the fifth state that allows naturopathic doctors DEA numbers. The DEA number is only good for the state it's registered in, but the number can be transferred to another state. However, if the naturopathic doctor will be practicing in more than one state, a DEA number for each state is required to prescribe controlled substances.

The Bureau Chief discussed the regulations modified text, which was included in the members' packets. Comments on the modified text were due to the Bureau by February 23, 2005; however, the Bureau did not receive any comments. Norine Marks briefly explained each section that was changed, which was indicated on the document by either a double underline to show added text or double strike through to indicate deleted text. The Bureau is now working on the final statement of reasons in order to complete the rulemaking file before July 6, 2005. The final statement of reasons and the entire rulemaking file are public documents and will be provided upon request. Dr. Hardy requested the Bureau to provide the members a copy of the final statement of reasons when they become available.

The Bureau Chief indicated committee appointments are still being made to the statutory committees. Dr. Khalsa, Dr. Hardy, Dr. Watson, Dr. Cates, ND, have been appointed to the Formulary Committee. Dr. Hange-Bauer, ND, and Dr. Field, ND, have been appointed to the Minor Office Procedures and the Bureau is making contacts with two emergency room doctors to also serve on this committee. The Bureau is making contacts for appointments to the Childbirth Attendance committee.

The Bureau Chief discussed the Bureau's budget. Revenue to date is approximately $113,000. The Bureau must pay back the $92,000 loan to Bureau of Automotive Repair this year. Repayment of the loan will deplete any reserves in the budget. The Bureau anticipates

some licensure revenue to come in September or October after NABNE releases its exam results.

III. Review of the Bureau's Strategic Plan

The Bureau Chief discussed the internal process of the strategic plan. A draft copy of the strategic plan is included in the members' packet for their review and comments.

There was some discussion under Goal One, page three of the document, in regards to 1.4 Establish re-certification examination by July 1, 2010. Dr. Hardy wanted to know if re-certification would apply to all applicants or could individuals be grandfathered in. The Bureau Chief indicated the re-certification is a legislative mandate that all naturopathic doctors take a re-certification exam after practicing for ten years.

There was some discussion under Goal Two, page three of the document, in regards to 2.2 Identify opportunities to participate in consumer and industry meetings and conferences to inform and education stakeholders about regulatory issues. Dr. Hardy wanted to know if the Bureau would obtain the input and advice from the Council on which meetings to attend and who should attend, such as the AANP conference in August 2005 held in Arizona. Dr. Hardy strongly suggested the Bureau attend the AANP conference since the California Council and licensure will be of significant interest for the conference attendees who may be applying for licensure in California. The Bureau Chief indicated that it is very difficult to get approval for any out-of-state travel. The Council discussed that the Community Outreach Ad-Hoc Committee could research and suggest events for the members or Bureau to attend.

The Bureau Chief mentioned that the Bureau is working with the Department's Complaint Mediation Unit to help set-up a process for handling complaints and with the Attorney General's Office for cite and fine format. In addition, the Bureau is in the process of developing disciplinary guidelines. Once the disciplinary guidelines are drafted the Bureau will distribute to the Council members for their review and input.

Once finalized, the strategic plan will be a public document and posted on the Bureau's website.

IV. Review of Legal Opinions

Norine Marks explained the first legal opinion, which was provided in the members' meeting packets, on Anabolic Steroids Exempt from Schedule III Controlled Substances. The Council discussed the legal questions and conclusions.

Questions: Are there forms of testosterone that are exempt from the list of controlled substances? Must a licensed naturopathic doctor register with the DEA prior to prescribing them?

Conclusion: The DEA, Office of Diversion Control, maintains a list of exempt anabolic steroids, which currently includes various forms and quantities of testosterone, including several patch

forms. Those products may still be considered prescription or "dangerous" drugs. NDs will need a furnishing number (issued by the Bureau) but not a DEA number to prescribe testosterone on the DEA's exempt list.

Norine Marks explained the second legal opinion, which was provided in the members' meeting packets, on Naturopathic Doctors; Prescribing. The Council discussed the four legal questions and conclusions.

Norine Marks further explained that NDs can independently prescribe exempt forms of hormone without a DEA number and without a supervising physician, but with a Bureau furnishing number. NDs can, also, independently prescribe non-exempt forms of hormones that are controlled substances without a supervising physician but must have a bureau furnishing number and a DEA number.

The Bureau will put together a FAQ sheet to include these legal opinions and post it on the website

The Council discussed the routes of administration of drugs and vitamins and discussed injectable forms (IM) of vitamins, such as B-12, herbal preparations, and homeopathic medicines. After some discusses, the Council requested a legal opinion on "*Can an ND independently administer these substances (vitamins, herbal preparation, and homeopathic medicines) in an IM route without a supervising physician based on the current language of the law*?" Norine Marks and the Bureau Chief will obtain the factual background on IM injections and Norine will prepare a legal opinion for the next Council meeting.

V. Discussion on Recertification Examination

Business and Professions Code 3634 (b) states *"the holder of a license under this chapter shall be required to take and pass a recertifying examination before the 10th anniversary of his or her initial licensure pursuant to this chapter. On or before July 1, 2010, the bureau shall establish standards for recertification and shall create a recertifying examination or adopt an existing examination that satisfies the recertification standards established by the bureau. In developing standards for recertification, the bureau shall consider information provided by the Council on Naturopathic Medical Education, naturopathic doctors, and other interested parties."*

The Bureau Chief informed the Council that the Bureau had submitted a budget change proposal (BCP) to obtain budget authority for fiscal year to work with the Office of Examination Resource (OER) Services, within the Department of Consumer Affairs. Because it takes at least three years for OER to develop an exam, the Bureau will need to start the exam development process in 2007. OER and the Bureau will consult with NABNE and NPLEX in the development of the recertifying exam. Jurisprudence may be an area to include in the recertifcation exam.

VI. Discussion on Ad Hoc Committees

The Chair explained that once the statutory committees are named for the Formulary Advisory Committee and Childbirth Attendance Advisory Committee, and the Minor Office Procedures Taskforce, then the Council's Ad Hoc committees will be disbanded. However, the Community Outreach Ad Hoc Committee will remain in tact.

The Chair Hangee-Bauer explained that recommendations reports are due to the legislature by January 1, 2006 and directed the members to review the Business and Professions Code Sections on Advisory Committees document in their meeting packets.

Based on the language of the law, Chairman Hangee-Bauer suggested the Formulary Advisory Committee should look at the following:

- what the naturopathic schools teach
- other states licensure and rules
- the trends of licensure of other states, for example are states expanding or take back what they are doing
- what NDs are practicing in
- review of the California law and its intent
- supervision requirement of an ND

Dr. Khalsa recommended that the Formulary Advisory Committee also look at the malpractice liability of a supervising physician, for an example how do the malpractice companies handle the supervising physician of a nurse practitioner, physician assistant, etc.?

The Council discussed the timetable for the recommendation reports. The Bureau must provide the recommendations to the legislature by January 1, 2006; however, the Bureau will need the recommendations from the various committees by November 15, 2005 for internal departmental and agency reviews.

The Council discussed that the statutory committee meetings will be public noticed, including any teleconference site. The Minor Office Procedures Taskforce is not a statutory committee; therefore, members will serve as consultants to the Bureau Chief.

As members of the Formulary Advisory Committee, Dr. Khalsa, Dr. Hardy, Dr. Watson, and Dr. Cates, ND, set the first Formulary Advisory Committee meeting for Sunday, June 25, 2005 at 3:00 p.m. at Dr. Khalsa medical office.

Chairman Hangee-Bauer appointed Daisy Ma to the Community Outreach Ad Hoc Committee. The main task is to develop a consumer information booklet for the Bureau on general questions about naturopathic medicine.

VII. Bureau Chief's Update

See above before item *III. Review of Bureau's Strategic Plan.*

VIII. Public Comment

Chairman Hangee-Bauer opened the floor for public comments. There were no public comments made during this period.

The next Council meeting is scheduled for Monday, September 19, 2005 in the Los Angeles area.

IX. Adjournment

The Council meeting was adjourned at 12:50 p.m.