



BUREAU OF NATUROPATHIC MEDICINE
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Agenda Item II

NATUROPATHIC MEDICINE ADVISORY COUNCIL

Meeting Minutes September 19, 2005

Junipero Serra State Building
 320 W. Fourth Street, 2nd Floor
 Pacific Conference Room
 Los Angeles, CA 90013

COUNCIL MEMBERS PRESENT: Carl Hangee-Bauer, ND, Chair
 Cynthia Watson, MD
 Soram Khalsa, MD
 Trevor Gates, ND
 Mary Hardy, MD
 David Field, ND
 Daisy Ma, Public Member

COUNCIL MEMBERS ABSENT: Alexandra Cock, Vice Chair

STAFF PRESENT: Norine Marks, Legal Counsel
 Linda Brown, Program Coordinator

I. Welcome and Call to Order

The meeting was called to order at 10:07 a.m. Roll call was taken and a quorum was declared.

II. Approval of the June 6, 2005 Meeting Minutes

The minutes were unanimously approved as corrected:

On page 4, Section 5, paragraph 2, at the end of line 2, "Office of Examinee Resources" should read "Office of Examination Resources."

In Section 6, paragraph 2, line 2, "July 1 2006" should read "January 1, 2006."

III. Chair Update

A. AANP Conference

Chairman Hangee-Bauer reported that at the recent Phoenix AANP convention, the California Naturopathic Doctor's Association held a forum and answered questions for students. Obstacles that were voiced to new doctors coming to California: 1) High cost of living in

California; 2) Scope of practice seen by students as being fairly limited in California. (e.g. limited formulary and prescriptive rights; minor surgery; and chiropractic issue, NDs are limited in naturopathic manipulation therapy; NDs cannot practice acupuncture in California.

B. Other trends, national issues

1) Idaho became 13th state to license naturopathic doctors. Movements are going on in other states.

2) Federal legislation regarding healthcare on Indian reservations includes naturopathic doctors in the language.

Chairman Hangee Bauer also stated his appreciation for all the hard work being done by the committees toward meeting the goals given by the Legislature.

IV. Bureau Update

Terri Ciau is now the acting Bureau Chief. Joanne Davis is absent; Linda Brown is filling in today.

A. Strategic Plan

The Strategic Plan is in the meeting packet. Dr. Cates stated she was curious about what was behind some of the things in the plan. It was decided that could be discussed at another time.

B. Bureau's Office Move

The Bureau is moving to the original Arco Arena building sometime in December. Members were given a sheet with the new address. Dr. Khalsa mentioned many of them got business cards with the Bureau's address, etc. and will probably need new cards with the new address and phone number on it. December 19th is the first day at the new building.

C. Budget

Linda Brown discussed the Bureau's fund condition. The \$92,000 start-up loan will be paid back to the program that loaned it to the Bureau. It will be transferred out of the Bureau's fund in December. At that point the budget will be a little bit tight.

The number of applications was discussed; as of last Friday there were 129 licensed NDs.

Dr. Hangee-Bauer stated that he spoke with Terri Ciau yesterday and she mentioned some budget concerns. A few years out, it gets even tighter. Fund condition shows -\$2000 at end of 2007/08. Estimate is 40 new licensees annually. There was discussion as to whether that was a high or low estimate and it was decided that 40 was reasonable.

The Bureau was started with the idea that it was to support itself, so that is why the number of applications is critical.

V. Legislation/Regulations:

A. Assembly Bill 302

Linda Brown reported on AB 302. The bill, if signed, would:

- Add NDs to the pharmacy laws.
- Extend the dates of 3 reports to the Legislature, from January 1, 2006 to January 1, 2007. [If the bill is not signed, the reports will need to be completed by November 1 to get through the approval process at the Department.]
- Add a provision so that Canadian applicants who passed a pre-NPLEX provincial exam in Canada can apply for licensure by 12/31/07.

The Governor has until October 9th to sign or veto the bill.

Norine Marks, legal counsel commented that she was unaware of the bill's existence until that day. She said the bill redefines "drug" to be in line with state law rather than federal law. She stated she was uncertain as to why changes in the pharmacy laws has distinctions made between an ND that is furnishing pursuant to 3640.5, which is supervised prescribing vs. 3640.7, which is independent right to prescribe. She did not have time to determine why one was being used versus another.

Gloria St. John, of the California Naturopathic Doctor's Association, commented that all changes to pharmacy laws were made with the Board of Pharmacy and stated that the bill also updates the name of the Association.

B. Status of Regulatory Package

Norine Marks discussed the regulatory package and said minor changes were made to the Final Statement of Reasons. The regulatory package was filed with the Secretary of State and became final on August 16.

Norine explained the regulatory process to the committee members.

Members asked if the regulations could be sent with the license. Norine explained that the notice of regulations is sent out to the interested parties list.

VI. Review of Draft Naturopathic Medicine Consumer Guide Brochure

Daisy Ma and Dr. Hangee-Bauer are the ad hoc consumer affairs committee. They are to prepare language for a consumer information brochure that is published by DCA for consumers outlining scope of practice, education, history, training, etc. Dr. Hangee-Bauer asked members to read through and make comments and send comments to Daisy Ma. A few comments that were made:

- Brochure may be legally correct, but is hard to understand for a consumer.
- 4th page at top says "in order to practice in California, NDs must do this ..." but it doesn't actually mention that you have to be licensed. Better to say "these are the requirements that make you eligible for licensure" or "in order to be licensed you have to ..."
- Prescriptive rights need to be clear, e.g. in order to prescribe you have to be issued a furnishing number.

VII. Review of Draft Disciplinary Guidelines

The draft was largely based on guidelines from other boards and bureaus in DCA. It is a very rough draft, first attempt, put together under very short timeframe. Disciplinary guidelines are used primarily by administrative law judges when disciplining a licensee to know what is expected. After comments from members and legal review, the guidelines would need to be adopted by regulation.

Dr. Hardy discussed the Medical Board's diversion program where licensees can voluntarily be put in a diversion program either for mental or addictive behavior without a formal restriction of their license. Dr. Hardy recommended considering it for this Bureau. Otherwise the only remedy is punitive and not therapeutic. Norine Marks stated that a diversion program begins in statute. Dr. Hardy would like something to be done about it before there is a licensee with a problem.

VIII. Review of IV Therapy Legal Opinion

Norine thanked Dr. Cates for providing a lot of the background of what IV therapy actually is. The conclusion is that NDs are authorized to practice IV therapy as long as he or she possesses the appropriate training, skills, and experience; and has prescriptive rights for the substance being delivered.

Dr. Hangee-Bauer remembers the question as being about IM therapy, rather than IV therapy. Norine stated she could prepare an opinion on IM therapy.

IX. CLIA

Gloria St. John, CNDA, reported that the Clinical Laboratory Improvement Act (federal regulations) regulate laboratory and requirements for laboratory directors. And also sets forth waived tests that can be administered without the supervision of laboratory directors. This federal act is administered in California by the Department of Health Services, which actually has adopted more stringent requirements so that waived tests are not recognized in California. The problem this presents for primary care practitioners such as naturopathic doctors is that they are unable to perform any testing in their offices and that includes testing such as a home pregnancy test; they can actually perform no test whatsoever. Although SB 907 does allow for laboratory testing as one of the authorities granted to naturopathic doctors. So CNDA is very concerned about this. There are also extremely stringent provisions for anyone who violates this. A first offense may be punishable by seven years in prison. So if you think about it, a primary care physician who cannot administer a pregnancy test in the office with this kind of penalty certainly is crippling the ability of the profession to practice legally and safely. What CNDA is asking the advisory council to do is to look at this issue and perhaps to make some recommendations to the Bureau while they are also pursuing their own independent strategy for getting some kind of relief to this provision in California. In other states, e.g. Washington and Oregon, naturopathic doctors are allowed to do waived tests. Other examples of waived tests are rapid strep, urine dipstick, glucose—the kind of things that people can buy at the drugstore and do themselves is not allowed to be done in a ND's office, unless the person administers the test themselves. MDs and DOs are able to do it in their offices. The B&P code section that needs to be modified is 4052.1. There are two approaches to this problem: 1) NDs can become recognized as laboratory directors; or 2) NDs can become authorized to perform waived tests, which is probably preferable. There are 17 pages of waived tests. ND Act allows NDs to order and perform laboratory tests, so there is a direct conflict between the laws. Dr. Watson suggested that they wait on the legal opinion and then make a recommendation based on the legal opinion.

X. Update on Naturopathic Statutory Committees

A. Formulary Advisory Committee (Dr. Khalsa)

The Formulary Committee has met 3 or 4 times since the last Advisory Council meeting. They expect that the Governor will sign AB 302 because it will be extremely difficult to get everything ready for the report by November 1.

IV Training – The committee has discussed extensively the IV training necessary and has had conversations with Dr. Virginia Osborne, a naturopathic physician from Oregon who has taught many IV courses to naturopathic doctors and they have discussed with her the format in which she has taught the 3-day course. The MDs on the committee which includes Dr. Khalsa, Dr. Watson, and Dr. Hardy, think that there should be a practical application also. So it would not just be hearing about IVs, but also, observing, starting and administering IV. It has generally been agreed upon by the committee that they will require a fourth day of documenting that the ND can actually do the technique safely and be prepared for emergencies. They are determining actually what the requirements are: how many IVs need to be witnessed, how many need to be started. They are also setting standards for who would be grandfathered in, and what training they would need to have. Many NDs are getting the training in the medical school programs for IVs, but not all. So if they can document their training, that may be enough. Otherwise, they are planning on setting up a course for the state of California which would probably be a 4-day course for NDs who wish to become certified to administer IVs.

The committee has also had extensive discussions about botanicals and their use parenterally (IM or IV). Dr. Hardy and Dr. Khalsa have reservations about the safety of this and the quality within the pharmaceutical and feel that the parenteral administration of herbal medicines really is a contentious issue and the committee is working on getting exact standards of quality of these and certification of quality before allowing an ND to administer them. Dr. Khalsa's initially felt that herbal medicines should not be allowed to be injected. However at a subsequent meeting, the committee decided that really close regulation of herbal medicines injected needs to be considered and should be an inclusionary list rather than an exclusionary list. If an herbal medicine is not on the list, it will not be available for injection.

The committee has also discussed medical malpractice insurance for MDs supervising NDs. There are concerns about what it is going to do in regards to malpractice risk and malpractice premiums. They do not have definite answers about that. There was a poll about malpractice suits against naturopathic physicians in other states and there have been 0-1 suits in the last 10 years. Joanne will have a report at the next meeting.

The committee is also discussing local anesthetics. NDs would like to be able to do neurotherapy, mesotherapy, and prolotherapy. There are no definite conclusions or recommendations at this point.

Dr. Hardy stated that the committee is struggling with how to write the regulations so that they don't restrict appropriate practice of well-trained professionals, and on the other hand, not leave it so vague that the public is not protected.

Dr. Field stated that he felt that NDs should be allowed the broadest ability within their training to recognize for instance, that a tincture is not sterile, etc., and shouldn't be injected.

Dr. Hangee-Bauer stated that if AB 302 is not signed that the committee reports are due to the Bureau Chief on November 1.

B. Childbirth Attendance Advisory Committee (Bureau)

The committee consists of two MDs, two midwives and two NDs. Linda Brown reported that the committee was short one MD that works in the academic field and one midwife. The committee was recently sent a letter stating that the committee is temporarily "on hold" and that the Bureau hoped that the extension for the report would pass. The Bureau has not received any inquiries from NDs interested in the childbirth attendance certificate. Dr. Hangee-Bauer stated that many people feel that this is an important option to have available for consumers.

C. Minor Surgery Committee (Dr. Field)

Dr. Field reported that the task force consists of himself, Dr. Hangee-Bauer. Linda Brown stated that two MDs have been appointed: Dr. Bruce Wapen and Dr. Bill Benda. These are the separate issues: 1) Study of the other state laws to determine what sort of standard of care. 2) What training is provided in the schools, so they are gathering course syllabi. 3) A study of actual practice of minor surgery in the field by naturopathic doctors. What are people actually doing? 4) Now that the two MDs are involved, they can also find out what MDs do in the state of California in the area of minor office procedures.

Dr. Cates commented that she knows of NDs in other states that are not coming to California because of minor surgery (e.g. mole removal, suturing, etc.).

XI. Future Advisory Council Meeting Dates

Dr. Hangee-Bauer recommended going to 3 meetings for next year, one in L.A., one in Oakland, one in Sacramento. A suggestion was made to cancel the December 5 meeting, and schedule the 2006 meetings for January, May, and September. The Council voted unanimously to cancel the December 5 meeting. The Council decided to meet on Sundays rather than Mondays. The meetings dates were scheduled as:

Sunday, January 29, Bay Area (preferably Oakland), 11:00 a.m.

Sunday, May 21, Sacramento, at DCA, 11:00 a.m.

Sunday, September 17, Burbank, 11:00 a.m.

It was discussed that Drs. Khalsa and Cates' terms are up in June 2006 and that they would have to re-apply. Ms. Marks will review the terms and appointing powers and discuss at the next meeting.

XII. Public Comment

Gloria St. John, CNDA, commented that the Association is available to the Bureau to keep the Bureau up to date on a lot of venues, activities, events, conferences to enable the Bureau to fulfill its Strategic Plan Goal 2.2, which is to "Identify opportunities to participate in consumer and industry meetings and conferences to inform and educate stakeholders about regulatory issues."

MD members at the first meeting asked about standards and practices of the profession,. Ms. St. John wanted to let them know that the Association has been finalizing standards and practices for naturopathic doctors as an association. They are in the final editing phase. Their question is how or whether such a document would be used in any disciplinary or regulatory actions of the Bureau so that the Association could have a view as to the possible uses of the document. The Association would like to know if it would have a place in the disciplinary or investigative activities.

Ms. Marks commented that it may. For example if a licensee is disciplined for negligence or incompetence, the standard of practice is always determined by the profession itself, what is actually being done. What value written guidelines would have is hard to say. Relevance would be determined on an individual basis.

XIII. Adjournment

The meeting was adjourned at 12:35.