Department of Consumer Affairs

NATUROPATHIC MEDICINE COMMITTEE

Committee Meeting

Monday, September 11, 2017
10:00 a.m.

TELECONFERENCE SITES

Main Meeting Location:

Department of Consumer Affairs
1747 North Market Blvd., Suite 186
Hearing Room
Sacramento, CA 95834

Naturopathic Medicine Committee
Phone: (916) 928-4785

[Page left blank]

TABLE OF CONTENTS

[Page left blank]

TAB 1

Agenda

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GOVERNOR EDMUND G. BROWN JR.

Naturopathic Medicine Committee
1300 National Drive, Suite 150, Sacramento, CA 95834
P (916) 928-4785 F (916) 928-4787 | www.naturopathic.ca.gov

NATUROPATHIC MEDICINE COMMITTEE NOTICE OF TELECONFERENCE MEETING

September 11, 2017
10:00 AM – Until the conclusion of business

Meeting Site:
Department of Consumer Affairs
1747 North Market Blvd., Ste. 186
HQ2 Hearing Room
Sacramento, CA 95834
(916) 928-4785

Teleconference Site(s):

The Center for Integrative Health
5620 Wilbur Ave., Suite 220
Tarzana, CA 91356

So. Cal. Men's Medical Group
9201 W. Sunset Blvd., Ste. 812
Los Angeles, CA 90069

Payless Shoe Source Bldg.
1180 S. Bristol St., #C, 2nd Floor
Santa Ana, CA 92704

One or more Committee members will participate in this meeting at the teleconference site(s) listed above. Each teleconference location is accessible to the public and the public will be given an opportunity to address the Committee at each teleconference location.

AGENDA

NOTE: The order of business is subject to change.

1. Call to Order and Roll Call / Establishment of Quorum

2. Public Comment for Items Not on Agenda

   The Committee may not discuss or take action on any item raised during this public comment section, except to decide whether to place the matter on the agenda of a future meeting. (Gov. Code §§ 11125, 11125.7(a).)

3. Discussion and Possible Action regarding Proposed Naturopathic Assistant (NA) Regulations.

4. Executive Officer's Update – Rebecca Mitchell

   a. Budget
   b. Enforcement Stats
   c. NMC Assessment - Findings and Corrective Actions

d. SB 796 (Hill) – NMC Oversight Hearing Bill Status
e. Clarification of Advertising Laws Update

5. DCA Update – Executive Staff

6. Discussion and Possible Action on Legislation for NMC to Pursue

a. Prescribing Privileges
b. Minor Office Procedures
c. Medical Cannabis Prescribing/Recommendations and Counseling
d. Authority to Supervise Nurses
d. Workers Compensation

7. Discussion and Possible Action regarding Subcommittee Drug Formulary Draft Recommendation

8. Review and Approval of Committee Meeting Minutes from May 15, 2017

9. Discussion and Possible Action on legislative proposal to establish a Fictitious Name Permit Program

10. Presentation on NMC Outreach Efforts

11. Establish Future Meeting Dates & Locations

12. Agenda Items for Future Meetings

13. Adjournment

For further information about this meeting, please contact Rebecca Mitchell at (916) 928-4785 or in writing at 1300 National Drive, Suite 150, Sacramento, CA 95834-1991. This notice can be accessed at www.naturopathic.ca.gov.

Government Code section 11125.7 provides the opportunity for the public to address each agenda item during or consideration by the Committee prior to the Committee taking any action on said item. Members of the public will be provided appropriate opportunities to comment on any issue before the Committee, but the Committee Chair may, at his or her discretion, apportion available time among those who wish to speak. Individuals may appear before the Committee to discuss items not on the agenda; however, the Committee can neither discuss nor take official action on these items at the time of the same meeting. (Gov. Code, sections 11125, 11125.7(a).)

In accordance with the Bagley Keene Open Meeting Act, all meetings of the Committee are open to the public and all meeting locations are accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting, may made a request by contacting Rebecca Mitchell, ADA Liaison, at (916) 928-4785 or via email at Rebecca.Mitchell@dca.ca.gov or may send a written request to the Committee's office at 1300 National Drive, Suite 150, Sacramento, CA 95834-1991. Providing you request to our office at least five (5)

business days before the meeting will help ensure availability of the requested accommodation(s).

TAB 2

Public Comments

Name of Public Providing Comment	Comment Presented

TAB 3

Naturopathic Assistants (NAs) Regulations

B&P Section 3640.2 and 3640.3 authorizes NAs and clarifies what the NA is allowed to do and what they are prohibited from doing.

Naturopathic Assistants

Senate Bill 1246 established Naturopathic Assistants effective January 1, 2011

Definition:

Naturopathic assistants (NA) perform technical and support services for licensed naturopathic doctors. They may perform certain medical procedures and technical support services under the supervision of a licensed naturopathic doctor. NAs are unlicensed.

Supervising ND Responsibilities:

Naturopathic doctors are solely responsible for training NAs and must be physically present on-site while the NA performs services.

Scope of Practice:

Naturopathic assistants may perform the following:

1. Administer medication by intradermal, subcutaneous, or intramuscular injections
2. Perform skin tests
3. Perform venipuncture or skin puncture in order to draw blood
4. Administer medications orally, sublingually, topically, vaginally, rectally, or by inhalation, as well as give medication to patients
5. Apply & remove bandages
6. Collect specimens for testing
7. Collect and record patient data including blood pressure and pulse
8. Perform simple lab and screening tests customarily performed in a medical office

NAs must place a written order or standing order prepared by a supervising ND in the patient's medical records.

Training:
Training is solely the responsibility of naturopathic doctors. NAs must have a minimum number of hours of appropriate training:

- 10 clock hours of training in administering injections and performing skin tests, and/or
- 10 clock hours of training in venipuncture and skin puncture for the purpose of withdrawing blood, and
- Satisfactory performance by the trainee of at least 10 each of intramuscular, subcutaneous, and intradermal injections and 10 skin tests, and/or at least 10 venipuncture and 10 skin punctures.

- For those administering medicine by inhalation, 10 clock hours of training in administering medical by inhalation.

Training **must** include instruction and demonstration in:

- pertinent anatomy and physiology appropriate to the procedures
- choice of equipment
- proper technique including sterile technique
- hazards and complications
- patient care following treatment or tests
- emergency procedures

Naturopathic Assistants
Business and Professions Code

3640.2. Notwithstanding any other provision of law, a naturopathic assistant may do all of the following:

(a) Administer medication only by intradermal, subcutaneous, or intramuscular injections and perform skin tests and additional technical support services upon the specific authorization and supervision of a licensed naturopathic doctor. A naturopathic assistant may also perform all these tasks and services in a clinic licensed pursuant to subdivision (a) of Section 1204 of the Health and Safety Code upon the specific authorization of a naturopathic doctor.

(b) Perform venipuncture or skin puncture for the purposes of withdrawing blood upon specific authorization and under the supervision of a licensed naturopathic doctor if prior thereto the naturopathic assistant has met the educational and training requirements for medical assistants as established in Section 2070. A copy of any related certificates shall be retained as a record by each employer of the assistant.

(c) Perform the following naturopathic technical support services:

(1) Administer medications orally, sublingually, topically, vaginally, or rectally, or by providing a single dose to a patient for immediate self-administration. Administer medication by inhalation if the medications are patient-specific and have been or will be repetitively administered to the patient. In every instance, prior to administration of medication by the naturopathic assistant, the naturopathic doctor shall verify the correct medication and dosage.

(2) Apply and remove bandages.

(3) Collect by noninvasive techniques and preserve specimens for testing, including urine, sputum, semen, and stool.

(4) Assist patients to and from a patient examination room or examination table.

(5) As authorized by the naturopathic doctor, provide patient information and instructions.

(6) Collect and record patient data, including height, weight, temperature, pulse, respiration rate, and blood pressure, and basic information about the presenting and previous conditions.

(7) Perform simple laboratory and screening tests customarily performed in a medical office.

(d) Perform additional naturopathic technical support services under the regulations and standards established by the committee. The committee shall, prior to the adoption of any regulations, request recommendations regarding these standards from appropriate public agencies, including, but not limited to, the Osteopathic Medical Board of California, the Medical Board of California, the Board of Registered Nursing, the Board of Vocational Nursing and Psychiatric Technicians of the State of California, the Laboratory Field Services division of the State Department of Public Health, and the Physical Therapy Examining Committee. The Naturopathic Medicine Committee shall also request recommendations regarding these standards from associations of medical assistants, physicians, and others, as appropriate, including, but not limited to, the Osteopathic Physicians and Surgeons of California, the California Medical Association, the California Society of Medical Assistants, and the California Medical Assistants' Association. Nothing in this

subdivision shall be construed to supersede or modify that portion of the Administrative Procedure Act that relates to the procedure for the adoption of regulations set forth in Article 5 (commencing with Section 11346) of Chapter 3.5 of Part 1 of Division 3 of Title 2 of the Government Code.

3640.3. (a) Nothing in this chapter shall be construed as authorizing the licensure of naturopathic assistants. Nothing in this chapter shall be construed as authorizing the administration of local anesthetic agents by a naturopathic assistant. Nothing in this chapter shall be construed as authorizing the Naturopathic Medicine Committee to adopt any regulations that violate the prohibitions on diagnosis or treatment in Section 2052.

(b) Nothing in this chapter shall be construed as authorizing a naturopathic assistant to perform any clinical laboratory test or examination for which he or she is not authorized under Chapter 3 (commencing with Section 1200).

(c) Notwithstanding any other provision of law, a naturopathic assistant may not be employed for inpatient care in a licensed general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

In busy ND offices, it is not uncommon to have one or more patients on IV therapy while the Doctor tends to other matters. It would be very helpful if a Naturopathic Assistant could perform additional technical support services to assist the Naturopathic Doctor during IV therapy.

Can the Naturopathic Medicine Committee investigate the feasibility of developing regulations for the following technical support services:

(1) Stop IV drip therapy under order from the ND. The order need not be patient specific.

(2) Withdraw a butterfly or catheter needle if the Naturopathic Assistant has a phlebotomy certification and, if necessary, additional training provided by the ND or an outside agency.

(3) Adjust the flow rate within a reasonable range, such as between 15 to 60 drops per minute, for vitamins, minerals, amino acids, glutathione, sugars, electrolytes, diluents and chelating agents under the supervision of an ND. ***Note:*** *This list is derived from the "Findings and Recommendations Regarding the Prescribing and Furnishing Authority of a Naturopathic Doctor (Recommendation #4: IV formulary)" issued by the Bureau of Naturopathic Medicine in January 2007.*

If, Naturopathic Assistants are able to perform these routine functions, it would greatly improve the function of busy Naturopathic Doctors offices. I understand that #3 (Adjust flow rate) may not be feasible and each proposal may require additional regulations, but #1 and #2 seem very straightforward for the Committee to consider adopting without hesitation.

TAB 4

Executive Officer's Update

AGENDA ITEM 4

Naturopathic Medicine Committee Meeting
Executive Officer Report
September 11, 2017

Licensing:

- There are **673** active licensees
- There are **17** inactive licensees
- There are **158** lapsed licenses
- There are **17** new-Part I applications pending
- There are **6** new-Part II applications pending
- There are **56** renewal applications pending

(Numbers as of 09/05/2017)

Enforcement:

The Committee, along with the assistance of the DCA staff, processed the enforcement backlog. On 06/20/2017 there were 65 cases pending in all various stages of investigations. The Committee and DCA staff closed all but 17 cases. The breakdown of the 17 cases are as follows:

- 3 are against NDs
- 1 is a case against an applicant
- 13 are against unlicensed individuals – (naturopaths or others) in violation of using the title of ND or practicing naturopathic medicine.

The investigative cost at the end of fiscal year end 2016-17 was $37,464 of the $32,000 enforcement encumbrance. An expense of $5,464 was over the enforcement budget.

For the reasons stated above, the staff recommended promoting legislation within the oversight bill SB 796 (Hill) for the "naturopath/naturopathic" title protection. Additionally, consumer outreach campaigns may alleviate the public confusion associated with "naturopath" vs. a naturopathic doctor.

NMC Assessment – Findings and Corrective Actions:

Throughout May and June 2017, the Department of Consumer Affairs (DCA/Department) conducted a review and assessment of the Committee's enforcement program. This included an audit of the review process and activities covering complaint intake, expert review, and investigations. There were several deficiencies noted within the program which included not having the established policies in written policies and procedure formats, not processing complaints in a timely manner, and not properly maintaining case files.

DCA provided the assistance of the Department's Division of Investigation (DOI), the Office of Information Services (OIS), and Internal Audits to identify and assist with implementing appropriate actions to mitigate the deficiencies.

Improvements were made in the Committee's enforcement program. The following are actions that were taken:

- Clean-up and update of over 50 completed cases in the BreEZe database (most were backlogged from the data conversion and manual entries that were made in error by temporary help). To date, there is no "backlog" in the Enforcement unit.
- Created physical files for each complaint that may not have had one.
- Review of case files to ensure that cases were appropriately worked and closed.

This effort covered 102 cases in BreEZe. Approximately, half of the cases were processed and closed appropriately, however, the system had some issues which prevented these cases being coded correctly. This issue caused cases to show as open even though they were closed.

New policy and procedure manuals for the Enforcement Unit are in the process of being created and are approximately 80-85% complete. These manuals should be completed by the end of November or first part of December 2017. Furthermore, staff has received additional training, including training that was more specific to the Committee. Staff has a better understanding of what the expectations are and is working to meet or exceed those performance measures.

DCA Executive Staff, along with DOI and ISO staff, have been a remarkable resource and we appreciate the collaborative efforts to get our enforcement program meeting the standards of the Department.

Budget Update:

At the fiscal year-end of 2016/17, the Committee had 14.7 months ($532,000) in reserve (copy of Fund Condition and Budget Reports are attached). It is anticipated that the budget for the current FY 2017/18 will be $433,000.

Planned receipts for FY 2016/17 revenue was $230,000. The actual receipts for FY 2016/17 revenue was $351,000. The staff is watching the trend for the first part of fiscal year 2017/18 (July – January), to determine if the increase in revenue will continue.

The Naturopathic Medicine Committee Fund is better than expected at this time because of the higher revenue collected during FY 2016/17. It is anticipated that FY 2017/18 may show similar revenue. If this holds true, the Committee will not show a shortfall until later than the anticipated insolvency date of FY 2019/20. This will provide the Committee with extra time to get the fee increase statutes and regulations in place.

Budget Highlights:

1. The fund remains unbalanced due to increased pro rata. This includes increased Division of Investigation (DOI) costs associated with enforcement. The Committee has started discussions of raising fees or implementing fees for services currently being provided at no charge, (for example, Out-of-State License Verification with Osteopathic Medical Board fee is $25).

   Senator Hill has agreed to author a fee ceiling increase bill during the next session. We will need to start a Fee Increase Regulation Package to raise the fees. This should occur concurrently with the bill (statute) change to complete the process in a timely manner.

2. Addition of the Fictitious Name Permit Program as discussed under agenda item 9 will also assist in balancing out the current fund condition.

3. The Committee needs to start preparing for a move or build-out of office space. Both the Committee and the Osteopathic Medical Board (OMBC) have out grown current office space. The Committee and OMBC have started conversations with DCA Facilities and Department of General Services to come up with the best option to complete the process within current fiscal resources. A decision has been made by both programs to stay in our current office space and make building improvements to maximize space and make additional space that can be used for new staff in the near future.

SB 769 (Hill) – NMC Oversight Hearing Bill Status

SB 796 is the sunrise bill for Naturopathic Medicine Committee. This bill will extend the sunset date to January 1, 2022. Unfortunately, the title protection language of the bill was removed due to opposition. However, the legislature, mostly the Assembly, has requested that the Committee track and log the data of unlicensed activity, including consumer harm at the end of a 12-month period. At that time, we can request a new title protection bill and they would be more comfortable with the changes to the Naturopathic Doctors Act at that time.

Medical Board of California is in support of our bill at this time. The bill is set to have a third reading for Asm. Floor on 9/6/17.

Clarification of Advertising Laws:

There is an increase of inquiries surrounding the general provisions, BPC 651 et seq. for advertising laws. The Committee has identified that this is something that should be updated in the Strategic Plan.

Committee should get suggestions from legal counsel on the most appropriate ways to answers some of the technical questions and provide the appropriate guidance to licensees.

Committee Member Training:

Committee Members are reminded to be sure to review the training requirements. All of the required training and the frequency of the training are included within this meeting material.

Once your training is complete, please be sure to submit your Certificates of Completion to the Executive Officer.

Licensing Population by Type

Board Code: 300

Data as of: Sep 5, 2017 2:31:09 PM

Licensing Population by Status			License Status							
			20	21	40	45	50	80	99	Total
			Current	CurrentInactive	Withdrawn	Delinquent	Cancelled	deceased	Deleted	
License Type	**License Type Long Name**	**Rank Short**								
3001	Naturopathic Doctor	ND	673	17	59	140	18	2	2	**911**
	3001 Total		**673**	**17**	**59**	**140**	**18**	**2**	**2**	**911**
Total			**673**	**17**	**59**	**140**	**18**	**2**	**2**	**911**

3069 - Naturopathic Medicine Committee
Analysis of Fund Condition

Prepared 9/6/17

(Dollars in Thousands)

2017 Budget Act

		ACTUAL PY 2016-17	Budget Act CY 2017-18	BY 2018-19	BY + 1 2019-20
BEGINNING BALANCE		$ 510	$ 532	$ 343	$ 146
Prior Year Adjustment		$ 1	$ -	$ -	$ -
Adjusted Beginning Balance		$ 511	$ 532	$ 343	$ 146
REVENUES AND TRANSFERS					
Revenues:					
125600	Other regulatory fees	$ 1	$ 1	$ 1	$ 1
125700	Other regulatory licenses and permits	$ 104	$ 30	$ 30	$ 30
125800	Renewal fees	$ 241	$ 212	$ 212	$ 212
125900	Delinquent fees	$ 1	$ 1	$ 1	$ 1
141200	Sales of documents	$ -	$ -	$ -	$ -
142500	Miscellaneous services to the public	$ -	$ -	$ -	$ -
150300	Income from surplus money investments	$ 4	$ -	$ -	$ -
160400	Sale of fixed assets	$ -	$ -	$ -	$ -
161000	Escheat of unclaimed checks and warrants	$ -	$ -	$ -	$ -
161400	Miscellaneous revenues	$ -	$ -	$ -	$ -
Totals, Revenues		$ 351	$ 244	$ 244	$ 244
Totals, Revenues and Transfers		$ 351	$ 244	$ 244	$ 244
Totals, Resources		$ 862	$ 776	$ 587	$ 390
EXPENDITURES					
Disbursements:					
1111	Program Expenditures (State Operations)	$ 308	$ 401	$ 409	$ 417
9990	Statewide Pro Rata Adjustment	$ 22	$ 32	$ 32	$ 32
Total Disbursements		$ 330	$ 433	$ 441	$ 449
FUND BALANCE					
Reserve for economic uncertainties		$ 532	$ 343	$ 146	$ -59
Months in Reserve		14.7	9.3	3.9	-1.5

NATUROPATHIC MEDICINE COMMITTEE - 3069
BUDGET REPORT
FY 2016-17 EXPENDITURE PROJECTION
Jun-2017

FISCAL MONTH 13

OBJECT DESCRIPTION	FY 2015-16 ACTUAL EXPENDITURES (MONTH 13)	FY 2015-16 PRIOR YEAR EXPENDITURES 6/30/2016	FY 2016-17 BUDGET STONE 2016-17	FY 2016-17 CURRENT YEAR EXPENDITURES 6/30/2017	FY 2016-17 PERCENT SPENT	FY 2016-17 PROJECTIONS TO YEAR END	FY 2016-17 UNENCUMBERED BALANCE
PERSONNEL SERVICES							
Salary & Wages (Staff)	57,960	57,960	70,000	63,352	90.5%	63,352	6,648
Statutory Exempt (EO)	79,430	79,430	64,000	78,933	123.3%	78,933	(14,933)
Temp Help Reg (Seasonals)	0	0	0	0	0.0%	0	0
Temp Help (Exam Proctors)	0	0	0	0	0.0%	0	0
Board Member Per Diem	0	0	0	0	0.0%	0	0
Committee Members (DEC)	1,400	1,400	4,000	2,800	70.0%	2,800	1,200
Overtime	223	223	0	0	0.0%	0	0
Staff Benefits	63,810	63,810	65,000	71,892	110.6%	71,892	(6,892)
TOTALS, PERSONNEL SVC	202,823	202,823	203,000	216,977	106.9%	216,977	(13,977)
OPERATING EXPENSE AND EQUIPMENT							
General Expense	1,157	1,157	7,000	1,063	15.2%	1,063	5,937
Fingerprint Reports	0	0	3,000	0	0.0%	0	3,000
Minor Equipment	3,747	3,747	0	0	0.0%	0	0
Printing	3,134	3,134	2,000	1,940	97.0%	1,940	60
Communication	753	753	3,000	1,257	41.9%	1,257	1,743
Postage	4	4	2,000	0	0.0%	0	2,000
Insurance	0	0	0	2	0.0%	2	(2)
Travel In State	4,520	4,520	3,000	447	14.9%	447	2,553
Travel, Out-of-State	0	0	0	0	0.0%	0	0
Training	299	299	1,000	426	42.6%	426	574
Facilities Operations	10,440	10,440	7,000	10,540	150.6%	10,540	(3,540)
Utilities	0	0	0	0	0.0%	0	0
C & P Services - Interdept	0	0	14,000	0	0.0%	0	14,000
C & P Services - External	2,935	2,935	5,000	4,123	82.5%	4,123	877
DEPARTMENTAL SERVICES:							0
Departmental Pro Rata	13,942	13,942	8,000	8,674	108.4%	8,674	(674)
Admin/Exec	23,975	23,975	24,000	23,907	99.6%	23,907	93
Interagency Services	10,000	10,000	0	0	0.0%	0	0
IA w/ OER	0	0	0	0	0.0%	0	0
DOI-ProRata Internal	983	983	1,000	920	92.0%	920	80
Public Affairs Office	2,000	2,000	4,000	3,852	96.3%	3,852	148
CCED	0	0	0	0	0.0%	0	0
INTERAGENCY SERVICES:							0
Consolidated Data Center	0	0	0	0	0.0%	0	0
DP Maintenance & Supply	398	398	2,000	999	50.0%	999	1,001
Central Admin Svc-ProRata	9,586	9,586	0	0	0.0%	0	0
EXAM EXPENSES:							0
Exam Supplies	0	0	0	0	0.0%	0	0
Exam Freight	0	0	0	0	0.0%	0	0
Exam Site Rental	0	0	0	0	0.0%	0	0
C/P Svcs-External Expert Administrative	0	0	0	0	0.0%	0	0
C/P Svcs-External Expert Examiners	0	0	0	0	0.0%	0	0
C/P Svcs-External Subject Matter	0	0	0	0	0.0%	0	0
ENFORCEMENT:							0
Attorney General	4,250	4,250	5,000	11,642	232.8%	11,642	(6,642)
Office Admin. Hearings	0	0	0	0	0.0%	0	0
Court Reporters	0	0	0	0	0.0%	0	0
Evidence/Witness Fees	600	600	0	600	0.0%	600	(600)
DOI - Investigations	76,708	76,708	27,000	25,222	93.4%	25,222	1,778
INVEST SVS-MBC ONLY	0	0	0		0.0%	0	
Major Equipment	0	0	0		0.0%	0	0
Special Items of Expense	0	0	0		0.0%	0	0
Other (Vehicle Operations)	0	0	0		0.0%	0	0
TOTALS, OE&E	169,431	169,431	118,000	95,614	81.0%	95,614	22,386
TOTAL EXPENSE	372,254	372,254	321,000	312,591	188%	312,591	8,409
Sched. Reimb. - External/Private			(1,000)	0	0.0%	(1,000)	0
Sched. Reimb. - Fingerprints					0.0%		0
Sched. Reimb. - Other					0.0%		0
Unsched. Reimb. - Other					0.0%		0
NET APPROPRIATION	372,254	372,254	320,000	312,591	97.7%	311,591	8,409
					SURPLUS/(DEFICIT):		2.6%

TAB 5

DCA Update

[Page left blank]

TAB 6

Possible Legislative Changes for NMC to Pursue

Possible Legislation for NMC to pursue:

- Prescribing Privileges
- Minor Office Procedures
- Medical Cannabis Prescribing/Recommendations and Counseling
- Authority to Supervise Nurses
- Workers Compensation

TAB 7

Drug Formulary Subcommittee Recommendations

Proposed Exclusionary Formulary

Licensed naturopathic doctors in California are excluded from prescribing the following drugs:

List #101 With Current MD/DO supervision

A) NIOSH list – table 1 = cytotoxic drugs
B) Antineoplastic drugs as defined in the table 1 NIOSH list for systemic administration
C) General anesthetics
D) Schedule I and II controlled substances

Note# 1: General IV therapy, IV antibiotics and IV and oral chelation are allowed only after completions of training/certification courses (see IV therapy regulations for allowed courses).

Note #2: All controlled substances require a DEA number by both the ND and supervising MD/DO.

List #102 Without Current MD/DO supervision

All medications are excluded **except** the following

A) All hormones including corticosteroids
B) Botanicals
C) Nutriceuticals
D) Vitamins
E) Minerals
F) Homeopathics
G) Amino acids
H) Emergency use of epinephrine, diphenhydramine, and oxygen

Note# 1: General IV therapy with allowed substances (see above) is allowed only after completion of a training/certification course (see IV therapy regulations for allowed courses)

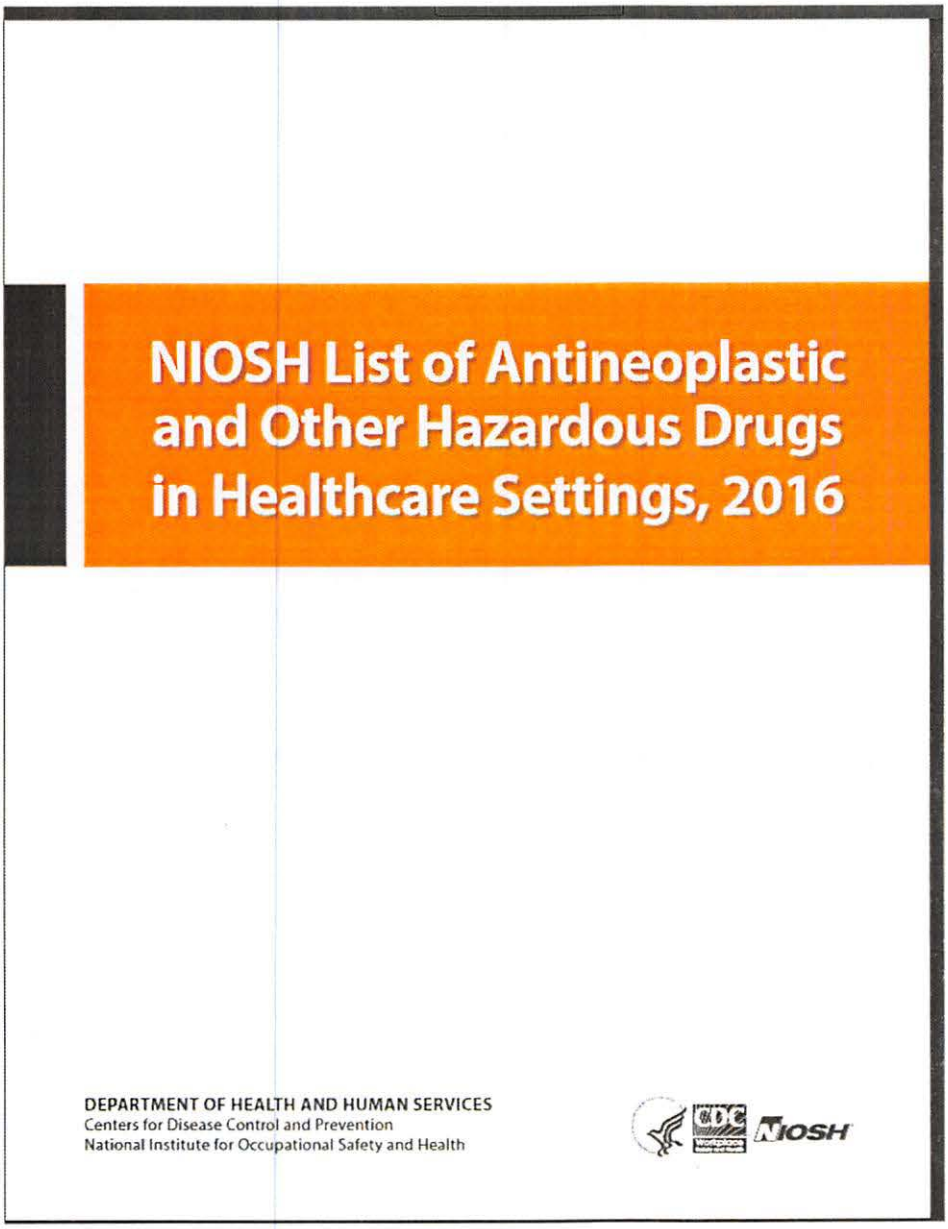
Note #2: All controlled substances (i.e. testosterone) require a DEA number

If MD/DO supervision is removed List #101 will become the formulary for all naturopathic doctors in California. The following requirements will be added for all licensees who wish to prescribe list #101 drugs.

A) A onetime pharmacy training course totaling 10 hours
B) Passage of a pharmacy certification exam
C) Continuation of current pharmacy CE requirements of 20 hours every 2 years with specific requirements in these pharmacy classes

1) at least 3 hours of training on antibiotics
2) at least 1 hour of training on anti-epileptics.
3) at least 2 hours of training on anti-hypertensives,
4) etc.....

You can find the link to the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016 link at:
https://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf



The drugs in **Table 1** meet one or more of the NIOSH criteria for a hazardous drug. In addition to many of these drugs being cytotoxic, the majority are hazardous to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, because they may be present in breast milk.

These drugs represent an occupational hazard to healthcare workers and should always be handled with use of recommended engineering controls and personal protective equipment (PPE), regardless of their formulation (IV [intravenous], SC [subcutaneous], topical, tablet, or capsule). Unopened, intact tablets and capsules may not pose the same degree of occupational exposure risk as injectable drugs, which usually require extensive preparation. Cutting, crushing, or otherwise manipulating tablets and capsules will increase the risk of exposure to workers. The manufacturer's safe-handling guidance (MSHG) is typically in Section 16 of the DPI. See Table 5 for safe-handling recommendations.

Abbreviations and footnotes. AHFS = American Hospital Formulary Service; MRHD = maximum recommended human dose.

*Drugs in red font were added in 2016.

National Toxicology Program classifications (http://ntp.niehs.nih.gov/pubhealth/roc/index.html): **Known To Be Human Carcinogens; ***Reasonably Anticipated To Be Human Carcinogens.

†International Agency for Research on Cancer (www.iarc.fr): Group 1, Carcinogenic to Humans; Group 2A, Probably Carcinogenic to Humans; Group 2B, Possibly Carcinogenic to Humans.

‡BCG, although classified as a vaccine, is used in the treatment of certain cancers. BCG should be prepared with aseptic techniques. To avoid cross-contamination, parenteral drugs should not be prepared in areas where BCG has been prepared. A separate area for the preparation of BCG suspension is recommended. All equipment, supplies, and receptacles in contact with BCG should be handled and disposed of as biohazardous. If preparation cannot be performed in a containment device, then respiratory protection, gloves, and a gown should be worn to avoid inhalation or contact with BCG organisms.

‡‡MSHG was removed in 2015 by the manufacturer.

Table 1. Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
abiraterone	10:00 antineoplastic agents		Women who are pregnant or may be pregnant should not handle without protection (e.g., gloves); FDA Pregnancy Category X	DailyMed; DrugBank
ado-trastuzumab emtansine	10:00 antineoplastic agents	yes	Conjugated monoclonal antibody; FDA Pregnancy Category D	DailyMed; DrugBank
afatinib*	10:00 antineoplastic agents		Special warnings on contraception for females while taking and 2 weeks post-treatment; FDA Pregnancy Category D	DailyMed; DrugBank

(Continued)

Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
altretamine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
amsacrine	NA antineoplastic agents	yes	IARC Group 2B†	DrugBank
anastrozole	10:00 antineoplastic agents		FDA Pregnancy Category X	DailyMed; DrugBank
arsenic trioxide	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category D	DailyMed; DrugBank
axitinib	10:00 antineoplastic agents		Teratogenic, embryotoxic and fetotoxic in mice at exposures lower than human exposures; FDA Pregnancy category D	DailyMed; DrugBank
azacitidine	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
Bacillus Calmette Guerin (BCG)	80:12 vaccines	yes	See special handling requirements‡; FDA Pregnancy Category C	DailyMed
belinostat	10:00 antineoplastic agents	yes	May cause teratogenicity and/or embryo-fetal lethality because it is a genotoxic drug and targets actively dividing cells; FDA Pregnancy Category D	DailyMed; DrugBank
bendamustine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
bexarotene	10:00 antineoplastic agents		FDA Pregnancy Category X	DailyMed; DrugBank
bicalutimide	10:00 antineoplastic agents		FDA Pregnancy Category X	DailyMed; DrugBank
bleomycin	10:00 antineoplastic agents	yes	IARC Group 2B; FDA Pregnancy Category D	DailyMed; DrugBank
bortezomib	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank

(Continued)

Table 1 (Continued) Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
bosutinib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
brentuximab vedotin	10:00 antineoplastic agents	yes	Conjugated monoclonal antibody; FDA Pregnancy Category D	DailyMed; DrugBank
busulfan	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; FDA Pregnancy Category D	DailyMed; DrugBank
cabazitaxel	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
cabozantinib	10:00 antineoplastic agents		Embryolethal in rats at exposures below the recommended human dose; FDA Pregnancy category D	DailyMed; DrugBank
capecitabine	10:00 antineoplastic agents	yes	Metabolized to 5-fluorouracil; FDA Pregnancy Category D	DailyMed; DrugBank
carboplatin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
carfilzomib	10:00 antineoplastic agents		Special warnings on contraception while taking and 2 weeks post- treatment; FDA Pregnancy category D	DailyMed; DrugBank
carmustine	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
chlorambucil	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category D	DailyMed; DrugBank
cisplatin	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
cladribine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
clofarabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank

(Continued)

Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
crizotinib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
cyclophosphamide	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category D	DailyMed; Drugbank
cytarabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
dabrafenib	10:00 antineoplastic agents		Special warnings on contraception for females while taking and 2 weeks post-treatment; FDA Pregnancy Category D	DailyMed; DrugBank
dacarbazine	10:00 antineoplastic agents	yes	NTP***; FDA Pregnancy Category C	DailyMed; Drugbank
dactinomycin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
dasatinib	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; Drugbank
daunorubicin	10:00 antineoplastic agents	yes	IARC Group 2B, AKA daunomycin; FDA Pregnancy Category D	DailyMed; Drugbank
decitabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; Drugbank
degarelix	10:00 antineoplastic agents	-‡‡	FDA Pregnancy Category X	DailyMed; Drugbank
docetaxel	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
doxorubicin	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
enzalutamide	10:00 antineoplastic agents		Embryo-fetal toxicity in mice at exposures that were lower than in patients receiving the recommended dose; FDA Pregnancy Category X	DailyMed; DrugBank

(Continued)

Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
epirubicin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; Drugbank
eribulin	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
erlotinib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
estramustine	10:00 antineoplastic agents	yes	FDA Pregnancy Category X	DailyMed; Drugbank
etoposide	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; FDA Pregnancy Category D	DailyMed; DrugBank
everolimus	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; Drugbank
exemestane	10:00 antineoplastic agents		FDA Pregnancy Category X	DailyMed; DrugBank
floxuridine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
fludarabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
fluorouracil	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
flutamide	10:00 antineoplastic agents		Indicated only for men; FDA Pregnancy Category D	DailyMed; DrugBank
fulvestrant	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
gemcitabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
gemtuzumab ozogamicin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
goserelin	10:00 antineoplastic agents		FDA Pregnancy Category X	DailyMed; Drugbank
histrelin	10:00 antineoplastic agents		Can cause fetal harm when administered to a pregnant patient, with the possibility of spontaneous abortion; FDA Pregnancy Category X	DailyMed; DrugBank

(Continued)

Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
hydroxyurea	10:00 antineoplastic agents	yes	Special warning on handling bottles and capsules; FDA Pregnancy Category D	DailyMed; DrugBank
idarubicin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
ifosfamide	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
imatinib	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
irinotecan	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
ixazomib	10:00 antineoplastic agents	yes	Male and female patients of childbearing potential must use effective contraceptive measures during and for 3 months following treatment	DailyMed; DrugBank
ixabepilone	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
letrozole	10:00 antineoplastic agents		FDA Pregnancy Category X	DailyMed; DrugBank
leuprolide	10:00 antineoplastic agents	yes	FDA Pregnancy Category X	DailyMed; DrugBank
lomustine	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
mechlorethamine	10:00 antineoplastic agents	yes	NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
megestrol	10:00 antineoplastic agents	yes	Nursing should be discontinued if megestrol is required; women at risk of pregnancy should avoid exposure; FDA Pregnancy Category X	DailyMed; DrugBank
melphalan	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category D	DailyMed; DrugBank

(Continued)

Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
mercaptopurine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
methotrexate	10:00 antineoplastic agents	yes	FDA Pregnancy Category X	DailyMed; DrugBank
mitomycin	10:00 antineoplastic agents	yes	IARC Group 2B; FDA Pregnancy Category D	DailyMed; DrugBank
mitotane	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
mitoxantrone	10:00 antineoplastic agents	yes	IARC Group 2B; FDA Pregnancy Category D	DailyMed; DrugBank
nelarabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
nilotinib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
omacetaxin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
oxaliplatin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
paclitaxel	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
panobinostat	10:00 antineoplastic agents	yes	Special warnings on contraception for females while taking and 1 month post-treatment;	DailyMed; DrugBank
pazopanib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
pemetrexed	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
pentostatin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
pertuzumab	10:00 antineoplastic agents		Black Box warning on embryo-fetal death and birth defects; FDA Pregnancy Category D	DailyMed; DrugBank

(Continued)

Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
pomalidomide	10:00 antineoplastic agents	yes	Females of reproductive potential must use two forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after stopping treatment; FDA Pregnancy Category X	DailyMed; DrugBank
ponatinib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
pralatrexate	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
procarbazine	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
regorafenib	10:00 antineoplastic agents		Black Box warning on severe and sometimes fatal hepatotoxicity; total loss of pregnancy at doses lower than recommended human dose; FDA Pregnancy Category D	DailyMed; DrugBank
romidepsin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
sorafenib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
streptozocin	10:00 antineoplastic agents	yes	IARC Group 2B; NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
sunitinib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
tamoxifen	10:00 antineoplastic agents		IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category D	DailyMed; DrugBank
temozolomide	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
temsirolimus	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank

(Continued)

Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
teniposide	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; FDA Pregnancy Category D	DailyMed; DrugBank
thioguanine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
thiotepa	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category D	DailyMed; DrugBank
topotecan	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
toremifene	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
trametinib	10:00 antineoplastic agents		Embryotoxic and abortifacient at doses less than recommended human dose; FDA Pregnancy Category D	DailyMed; DrugBank
trifluridine/tipiracil (combination only)	10:00 antineoplastic agents	yes	Embryo-fetal lethality and embryo-fetal toxicity at doses lower than or similar to exposures at the recommended human dose	DailyMed; DrugBank; DrugBank
triptorelin	10:00 antineoplastic agents		FDA Pregnancy Category X	DailyMed; DrugBank
valrubicin	10:00 antineoplastic agents	yes	FDA Pregnancy Category C	DailyMed; DrugBank
vandetanib	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
vemurafenib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
vinblastine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
vincristine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
vinorelbine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank

(Continued)

Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
vismodegib	10:00 antineoplastic agents		Black Box warning on embryo-fetal death or severe birth defects; recommend effective contraception for females during therapy and for 7 months after treatment; present in semen; no sperm donation during and 3 months post-treatment; FDA Pregnancy Category D	DailyMed; DrugBank
vorinostat	10:00 antineoplastic agents	yes	Adverse embryo-fetal effects at less than the recommended human dose; FDA Pregnancy Category D	DailyMed; DrugBank
ziv-aflibercept	10:00 antineoplastic agents		Embryotoxic and teratogenic in rabbits at exposure levels lower than human exposures at the recommended dose, with increased incidences of external, visceral, and skeletal fetal malformations; FDA Pregnancy Category C	DailyMed; DrugBank

TAB 8

Meeting Minutes for Review/Approval

May 15, 2017

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GOVERNOR EDMUND G. BROWN JR.

Naturopathic Medicine Committee
1300 National Drive, Suite 150, Sacramento, CA 95834
P (916) 928-4785 F (916) 928-4787 | www.naturopathic.ca.gov

Naturopathic Medicine Committee

DRAFT

Meeting Minutes

May 15, 2017

COMMITTEE MEMBERS PRESENT:	David Field, ND, Lac, Chair Tara Levy, ND, Vice-Chair Greta D'Amico, ND Michael Hirt, MD Thyonne Gordon, PhD Gregory Weisswasser, ND Alexander Kim Dara Thompson, ND
COMMITTEE MEMBERS ABSENT:	Myles Spar, MD
STAFF PRESENT:	Ryan Marcroft, Esq., Legal Counsel Rebecca Mitchell, Executive Officer (EO)
Persons of Interest	Yeaphana LaMarr, Analyst, DCA, Leg. & Reg. Review Unit Mark Ito, Budget Analyst, DCA Budget Unit Jonathan Burke, DCA, Executive Office Judy Wolen, on behalf of CNDA

1. **Welcome & Call to Order**
   The meeting was called to order at 10:07 a.m.

2. **Establishment of a Quorum**
   Roll Call was taken and quorum was established.

3. **Public Comment for Items Not on Agenda**
   There were no public comments.

4. **Appointment of Drug Formulary Subcommittee Member Replacement**
Dr. Dara Thompson, ND, was interested in the nomination for the Drug Formulary Subcommittee member replacing Dr. Koren Barrett, ND.

Additionally, Dr. Peter Koshland, PharmD and Dr. Michael Hirt, MD, were also interested in continuing as a member of the subcommittee.

Dr. David Field, ND, Chair, appointed Dr. Thompson as the newest member of the Drug Formulary Subcommittee to sit alongside of Dr's. Koshland and Hirt.

5. **Drug Formulary Discussion/Action:**
The Committee discussed the reason for creating an exclusionary drug formulary. The creation of the formulary is needed for two (2) reasons:

1. This document was mandated by the legislature and was the intent to have the program give recommendations for the formulary based on the training and education of the NDs.
2. To assist licensees in determining what drugs are allowed to be prescribed, administered, and furnished within their scope of practice.

Dr. D'Amico requested that a correction be made to a typographical error found on the January 27, 2014 document of the Formulary Subcommittee Report to the Naturopathic Medicine Committee document. This correction will be made and the amended form will be reposted to the Committee's website.

6. **Creation of a Naturopathic Childbirth Attendance Application Process**
The Committee is interested in creating regulatory language to clarify the statutory authority of BPC sections 3650 through 3655 et. seq.

Committee Member D'Amico, states that the current statutes are confusing and was not sure what the original intent was designed to do. Dr. Tara Levy, ND, Vice-Chair stated that some parts of the statute relating to naturopathic childbirth attendance is outdated and should be revisited and cleaned up prior to creating the regulatory language.

The Chair appointed Dr. Levy as subcommittee member for the purpose of cleaning up statutory language and clarifying within regulations. Dr. Levy will also consult with outside subject matter experts (SMEs) who could assist with this project.

7. **Proposed Regulatory Language to Implement "Naturopathic Committee – Notice to Consumer" signage: Implementation of BPC 138:**
The Committee approved the proposed regulatory language recommended by the staff. The regulation would clarify the general provisions of BPC sections 138 and 680.

Motion – Weisswasser / Second – Levy, to approve proposed language for implementation of BPC sections 138 and 680, start regulation process, and add information regarding the upcoming changes to the website. Roll call vote taken,

motion carried 8-0-0. (YES – Field, Levy, D'Amico, Hirt, Gordon, Thompson, Weisswasser, Kim / NO – none / Abstentions – none).

8. **Meeting Minutes for Review/Approval:**
   - Approval for Meeting minutes of February 6, 2017

Motion – D'Amico / Second – Weisswasser, to approve 2/6/17 meeting minutes as submitted with no amendments. Roll call vote taken, motion carried 8-0-1. (YES – Field, Levy, D'Amico, Gordon, Thompson, Weisswasser, Kim / NO – none / Abstentions – Spar).

9. **Budget Update – DCA Budget Staff**
Mark Ito, DCA Budget Analyst, reported on the Committee's current budget. (Included in the meeting material.)

The Budget office and Committee staff has identified that there is an issue with the fund being unbalanced. This issue is the result of adding an additional staff to assist in carrying out the licensing and enforcement workload, along with an increase to DCA and other State Agency pro rata. Mr. Ito has suggested that staff and the budget office work collaboratively to request a raise in the fee ceiling. Unfortunately, a fee cap was placed at the current fee structure in the Committee's sunset bill, SB 796 (Hill). Amendments to SB 796 can be made to the third reading of the bill.

The Committee has directed the EO to request a fee change amendment to SB 796 with Senator Hill's office. Proposed caps for the fees are trending at being raised by no less than 25% of current fee.

10. **Establishment of a Proposed Fictitious Name Permit Program:**
In prior meetings, the proposed language for a Fictitious Name Permit Program was adopted by the Committee. The Committee now must establish a fee structure for the new permitting process.

The Committee would like to have the following fee structure included with the proposed FNP bill language.

Fee Type	Min. / Max. Fee	Set Fee by Regulation
FNP Application Fee (1yr)	$75/$150	$100
FNP Renewal Fee (Dec 31 Exp)	$50/$100	$50
FNP Delinquent Fee	Not to exceed $25	$25

Motion – Levy / Second – Weisswasser, to add fee structure to the proposed language for the FNP Program and find author. Roll call vote taken, motion carried 8-0-0. (YES – Field, Levy, D'Amico, Hirt, Gordon, Thompson, Weisswasser, Kim / NO – none / Abstentions – none).

11. Legislative Update – DCA Legislative and Regulatory Review Staff

The Committee's legislative analyst, Yeaphana LaMarr, gave an update regarding sunset bill SB 796. She continues to offer her services throughout the remainder of the sunset process.

Additionally, Ms. LaMarr reported on the status of the bill on the agenda. The Committee took the following stances on the bills as outlined:

- SB 746 (Portantino) – no action
- SB 796 (Hill) – continuing support stance
- AB 12 (Cooley) – no action
- AB 77 (Fong) – no action
- AB 208 (Eggman) – oppose, for major concerns over enforcement issues as it pertains to substance abusing licensees and risk to consumers
- AB 241 (Dababneh) – no action
- AB 349 (McCarty) – no action
- AB 492 (Grayson) – no action
- AB 703 (Flora) – no action
- AB 710 (Wood) – no action
- AB 767 (Quirk-Silva) – no action
- AB 827 (Rubio) – no action
- AB 835 (Dababneh) – no action
- AB 1005 (Calderon) – no action
- AB 1053 (Calderon) – no action
- AB 1190 (Obernolte) – no action
- AB 1615 (Garcia) – no action
- SB 27 (Morrell) – no action
- SB 496 (Cannella) – no action
- SB 715 (Newman) – no action
- AB 40 (Santiago) – no action
- AB 508 (Santiago) – no action
- SB 43 (Hill) – no action
- SB 419 (Portantino) – no action
- SB 572 (Stone) – no action
- SB 762 (Hernandez) – no action

Motion – Weisswasser / Second – Levy, to take stance on legislative bills as outlined above. Roll call vote taken, motion carried 8-0-0. (YES – Field, Levy, D'Amico, Hirt, Gordon, Thompson, Weisswasser, Kim / NO – none / Abstentions – none).

12. Establish Future Meeting Dates & Locations

The next meeting will be scheduled tentatively as follows:

- September 11, 2017 at 10:00 a.m. – Sacramento, CA and teleconference options
- December 04, 2017 – Teleconference meeting if business needs exist for SB 796 implementation.

13. Agenda Items for Future Meetings

- Regulation language examples for proposed FNP program
- Drug Formulary Subcommittee recommendations

14. Adjournment

There being no further business or public comment, the meeting was adjourned at 1:44 p.m.

TAB 9

Fictitious Name Permit Program

Proposed Language – Fictitious Name Permits (Addition of BPC 3670.1 and 3674.1)

3670.1

The use of any fictitious, false, or assumed name, or any name other than his or her own by a licensee either alone, in conjunction with a partnership or group, or as the name of a professional corporation, in any public communication, advertisement, sign, or announcement of his or her practice without a fictitious-name permit obtained pursuant to Section 3674.1 constitutes unprofessional conduct. This section shall not apply to the following:

(a) Licensees who are employed by a partnership, a group, or a professional corporation that holds a fictitious name permit.

(b) Licensees who contract with, are employed by, or are on the staff of, any clinic licensed by the State Department of Health Services under Chapter 1 (commencing with Section 1200) of Division 2 of the Health and Safety Code.

(c) Any medical or naturopathic medical school approved by the division or a faculty practice plan connected with the school.

3674.1

(a) Any naturopathic doctor, who as a sole proprietor, or in a partnership, group, or professional corporation, desires to practice under any name that would otherwise be a violation of Section [above code] may practice under that name if the proprietor, partnership, group, or corporation obtains and maintains in current status a fictitious-name permit issued by the Naturopathic Medicine Committee, under the provisions of this section.

(b) The committee shall issue a fictitious-name permit authorizing the holder thereof to use the name specified in the permit in connection with his, her, or its practice if the committee finds to its satisfaction that:

(1) The applicant or applicants or shareholders of the professional corporation hold valid and current licenses as naturopathic doctors.

(2) The professional practice of the applicant or applicants is wholly owned and entirely controlled by the applicant or applicants.

(3) The name under which the applicant or applicants propose to practice is not deceptive, misleading, or confusing.

(c) Each permit shall be accompanied by a notice that shall be displayed in a location readily visible to patients and staff. The notice shall be displayed at each place of business identified in the permit.

(d) This section shall not apply to licensees who contract with, are employed by, or are on the staff of, any clinic licensed by the State Department of Health Services under Chapter 1 (commencing with Section 1200) of Division 2 of the Health and Safety Code or any medical or naturopathic medical school approved by the division or a faculty practice plan connected with that school.

(e) The committee shall establish procedures for the renewal of fictitious-name permits every as frequent as one (1) year or up to two (2) years on an anniversary basis. For the purpose of the conversion of existing permits to this schedule the committee may fix prorated renewal fees.

(f) The committee may revoke or suspend any permit issued if it finds that the holder or holders of the permit are not in compliance with the provisions of this section or any regulations adopted pursuant to this section. A proceeding to revoke or suspend a fictitious-name permit shall be conducted in accordance with Section 3663.

(g) A fictitious-name permit issued to any licensee in a sole practice is automatically revoked in the event the licensee's certificate to practice naturopathic medicine is revoked.

(h) The committee may delegate to the executive officer, or to another official of the board, its authority to review and approve applications for fictitious-name permits and to issue those permits.

FNP Fees

FNP Application Fee (1 Yr)	Min $75 – not to exceed $150	Set at $100
FNP Renewal (12/31 exp)	Min $50 – not to exceed $100	Set at $50
FNP Delinquent Fee	Not to Exceed $25	Set at $25

TAB 10

Presentation on NMC Outreach Efforts

STATE OF CALIFORNIA

DEPARTMENT OF CONSUMER AFFAIRS

NATUROPATHIC MEDICINE COMMITTEE

Dr. David Field, ND, LAc, Chair
Dr. Tara Levy, ND, Vice Chair
Rebecca Mitchell, Executive Officer

Medical Board of California meeting
July 28, 2017

Topics of Discussion

- What is Naturopathy
- What are Naturopathic Doctors (ND)
- Education of Naturopathic Doctors
- Safety Records
- Malpractice
- Formularies
- Scopes

What is Naturopathy?

- Naturopathic Medicine is a distinct and comprehensive system of primary health care that uses primarily natural methods and substances to support and stimulate the body's self-healing process.

- In 2003, California became the 13th state to recognize the profession and provided licensure to naturopathic doctors.
- Currently 17 states, the District of Columbia, and the US territories of Puerto Rico and the US Virgin Islands have licensing laws for naturopathic physicians.
- In most of the other licensing states and territories, NDs are titled as naturopathic physicians.

Naturopathic Philosophy

- First, Do No Harm
- Identify and Treat the Cause
- Doctor as Teacher
- Treat the Whole Person
- Prevention

What are Naturopathic Doctors (ND)?

Naturopathic Doctors

Naturopathic Doctors are trained in a wide variety of primary care, complementary and alternative therapies, including:

- Conventional Medications and Drugs
- Minor Office Procedures
- Naturopathic Childbirth Attendance
- Hormone Replacement Therapies
- Herbal and Homeopathic Medicines
- Clinical Nutrition and Diet
- Vitamins, Amino Acids, Minerals, Enzymes, and Nutraceuticals
- Physical Medicine such as Massage, Bodywork, Exercise Therapy, and Hydrotherapy
- Counseling and Behavioral Therapies
- Health and Lifestyle Counseling

Education of Naturopathic Doctors

Naturopathic Education

- Bachelor's Degree from a regionally accredited college or university
- ND Degree or diploma of a minimum 4,100 total hrs. in basic and clinical sciences, naturopathic philosophy, naturopathic modalities, and naturopathic medicine.
- Not less than 2,500 hrs. shall consist of instruction.
- Not less than 1,200 hrs. shall consist of supervised clinical training.
- NDs are clinically trained in both natural and conventional approaches to medicine.
- NDs are required to complete at least 72 hrs. of pharmacology course hours in school and must complete a minimum of 20 hours of pharmacotherapeutic training every two years of their continuing education requirement.

Standards of Naturopathic Education

The Counsel of Naturopathic Medical Education (CNME) sets the standards for naturopathic colleges in the areas of finances, faculty education, ethics, program development, education, and clinical competencies.

Standards of Naturopathic Education

Basic & Diagnostic Sciences	Anatomy, neuroanatomy, neurosciences, physiology, histology, pathology, biochemistry, genetics, microbiology, immunology, lab diagnosis, clinical diagnosis, physical diagnosis, medical research, epidemiology, public health, medical ethics, and others.
Clinical Sciences	Family medicine, ENT, cardiology, pulmonary medicine, gastroenterology, rheumatology, neurology, dermatology, urology, infectious disease, pediatrics, geriatrics, obstetrics, gynecology, pharmacology, pharmacognosy, minor surgery, ophthalmology, psychiatry, and others.
Naturopathic Therapeutics	Clinical nutrition, botanical medicine, homeopathy, naturopathic manipulative therapy, hydrotherapy, lifestyle counseling, naturopathic philosophy, naturopathic case management, advanced naturopathic therapies, acupuncture and traditional Chinese medicine, & Ayurvedic medicine.

Source: Handbook of Accreditation for Naturopathic Medicine Programs. *Counsel of Naturopathic Medical Education* April 2016; 34-52

Typical Educational Breakdown by Year:

- **First year** studies include the normal structure and function of the body with solid introduction to naturopathic theory, philosophy, and therapeutics.
- **Second year** focuses on the study of disease and diagnosis while beginning course work in botanical medicine, therapeutic manipulation, clinical nutrition, and homeopathic medicine sequences. To enter into the clinical training of the third year, students must pass all basic science courses and diagnostic courses, as well as a clinic entrance examination.

Typical Educational Breakdown by Year:

- **Third year** continues focusing on the botanical medicine, manipulation, clinical nutrition, and homeopathic medicine sequences, begins the organ systems courses (which emphasize case management), and gives major emphasis to clinical training. Students must pass a clinical primary status exam to proceed in the clinic.
- **Fourth year** continues the organ systems courses. The major focus of the fourth year is practical clinical training, working side by side with licensed physicians caring for patients. A clinic proficiency exam ensures clinical competency prior to graduation.

Comparison of the Basic Science Education

	Naturopathic	Allopathic	Osteopathic
Anatomy (gross &dissection)	350	380	362
Physiology	250	125	126
Biochemistry	125	109	103
Pharmacology	100	114	108
Pathology	125	166	152
Microbiology / Immunology	175	185	125
TOTAL HOURS	**1,125**	**1,079**	**976**

Above is a comparison of the basic science education of naturopathic doctors to that of an allopathic or osteopathic physician and surgeon, according to the Journal of Family Practice.

Naturopathic Physicians Licensing Examination (NPLEX)

California and all other licensing states require naturopathic physicians to pass Parts I and II of the NPLEX. The NPLEX is a rigorous, nationally standardized licensing exam implemented in 1986, replacing individual state exams.

- **NPLEX Part I**: Biomedical Science Examination is an integrated, case-based examination that covers the topics of anatomy, physiology, biochemistry & genetics, microbiology & immunology, and pathology. This examination is designed to test whether the examinee has the scientific knowledge necessary for successful completion of clinical training.
- **NPLEX Part II**: Core Clinical Science Examination is an integrated case-based examination that covers the following topics: diagnosis (using physical & clinical methods, lab tests & imaging studies), materia medica (botanical medicine and homeopathy), nutrition, physical medicine, health psychology, emergency medicine, medical procedures, public health, pharmacology, and research. This examination is designed to test the skills and knowledge that an entry-level naturopathic physician must have in order to practice safely.

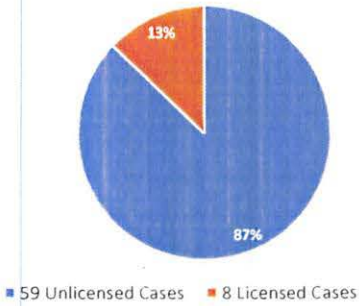
Safety Records

Naturopathic Doctors have the Best Safety Records

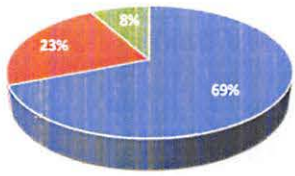
- The Naturopathic Medicine Committee rarely receives complaints about licensed naturopathic doctors
- Majority of complaints are for unlicensed practice violations.

Types of Enforcement Cases

Licensed vs. Unlicensed Cases



Licensee Case Violation Types



Malpractice Insurance

Malpractice Insurance

- Most malpractice companies issue the same policy to NDs vs. other healing arts professionals for half the cost due to low risk factors of naturopathic medicine.
- Malpractice claims are lowest for ND profession across the nation.

Drug Formularies

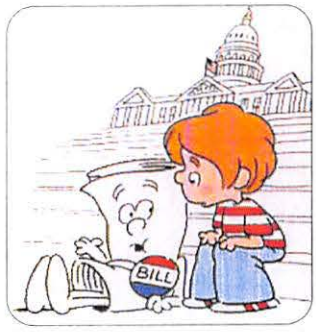
Drug Formularies for Naturopathic Doctors

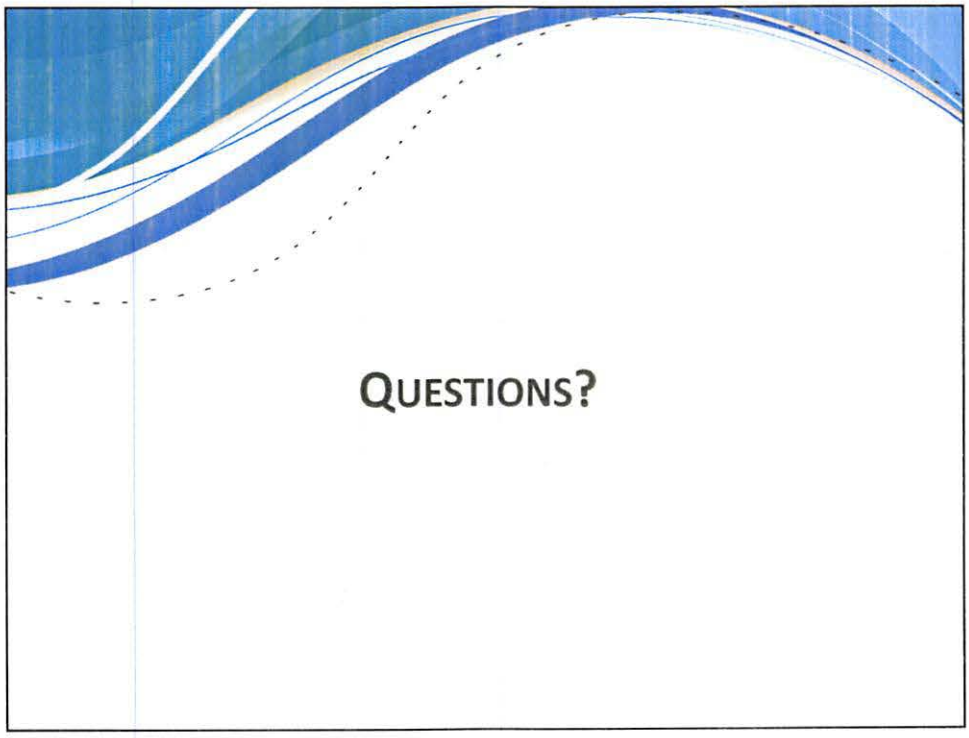
- Most ND Regulatory Boards allow Independent Prescribing of:
  - Schedule III through V Controlled Substances
  - All Legend Drugs
  - Hormones (natural and synthetic)
  - Natural Substances
- Formularies
  - Exclusionary

Naturopathic Scopes

Naturopathic Medicine Scope

- In most states includes minor office procedures and independent prescribing rights.
- California is limited in its scope, but the Committee plans to implement the Legislature's original intent to include the minor office procedures and independent prescribing rights by sponsoring a scope bill.




QUESTIONS?

TAB 11

Establish Future Meeting Dates and Locations

Naturopathic Medicine Committee

Establish Future Meeting Dates and Locations

Dates	***Locations***
*Winter Meeting December 04, 2017	Teleconference meeting
Spring 2018 Meeting	
Summer 2018 Meeting	

*The 12/04/17 meeting was decided upon during the 5/15/17 NMC Meeting. This meeting has been scheduled as a teleconference meeting only, if there is business need surrounding the SB 796 (Hill) Sunset Bill.

NOTE: *Please keep in mind costs associated with meeting when choosing locations for meetings.*

TAB 12

Agenda Items for Future Meetings

Naturopathic Medicine Committee

Agenda Items for Future Meetings

Agenda Item	***Requestor***