

Department of Consumer Affairs



Intravenous (IV) Therapy

Subcommittee Meeting

Wednesday, January 22, 2020

10:00 a.m. – 11:00 a.m.

TELECONFERENCE SITES

Main Meeting Location:

Department of Consumer Affairs
1625 North Market Blvd., Suite N-220
El Dorado Room
Sacramento, CA 95834

Naturopathic Medicine Committee
Phone: (916) 928-4785

TABLE OF CONTENTS

TAB 1	Agenda
TAB 2	Public Comments
TAB 3	Discussion and Possible Approval of Intravenous and Injection Therapy Regulatory Language: <ul style="list-style-type: none">a) Proposed language – §4237.1 Training Requirements for Certification. Intravenous Therapyb) Proposed language - §4237.2 Training Requirements for Certification. Injection Therapyc) Proposed language - §4237.3 Intravenous and Injection Therapy. Office Requirementsd) Proposed language - §4237.4 Intravenous and Injection Therapy. Staffing Requirements
TAB 4	Review and Approval of 12/16/2019 Meeting Minutes
TAB 5	Establish Future Meeting Dates and Locations
TAB 6	Agenda Items for Future Meetings

TAB 1

Agenda



**Subcommittee
Members**

Dara Thompson, ND
Vera Singleton, ND
Virginia Osborne, ND

**NATUROPATHIC MEDICINE COMMITTEE
IV THERAPY SUBCOMMITTEE
AGENDA AND NOTICE OF TELECONFERENCE MEETING**

Wednesday, January 22, 2020
10:00 AM to 11:00 AM

Teleconference Locations:

Department of Consumer Affairs
1625 North Market Blvd.
El Dorado Room – Ste. N-220
Sacramento, CA 95834

(No Board members will be at the Sacramento location;
it is offered as an additional location for staff and the public)

Office of Virginia Osborne, ND
13904 Meadow View Dr.
Grass Valley, CA 95945-9007

Azzolino Chiropractic Neurology &
Integrative Wellness
1545 Broadway
Ground Floor
San Francisco, CA 94109

Each teleconference location is accessible to the public and the public will be given an opportunity to address the Subcommittee 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 Subcommittee 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 Approval of Intravenous and Injection Therapy
Regulatory Language:
 - a. Proposed language - §4237.1 Training Requirements for Certification. Intravenous Therapy
 - b. Proposed language - §4237.2 Training Requirements for Certification. Injection Therapy
 - c. Proposed language - §4237.3 Intravenous and Injection Therapy. Office Requirements
 - d. Proposed language - §4237.4 Intravenous and Injection Therapy. Staffing Requirements

4. Review and Possible Approval of Meeting Minutes:
 - a. December 16, 2019 Meeting Minutes
5. Establish Future Meeting Dates and Locations
6. Agenda Items for Future Meetings
7. 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 consideration by the Subcommittee prior to the Subcommittee taking any action on said item. Members of the public will be provided appropriate opportunities to comment on any issue before the Subcommittee, but the Subcommittee Chair may, at his or her discretion, apportion available time among those who wish to speak.

Individuals may appear before the Subcommittee to discuss items not on the agenda; however, the Subcommittee 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 Subcommittee 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 make 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 Naturopathic Medicine Committee's office at 1300 National Drive, Suite 150, Sacramento, CA 95834-1991. Providing your 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

Discussion and Possible Approval of
Intravenous and Injection Therapy Regulatory
Language

a) Proposed language - §4237.1 Training Requirements for
Certification. Intravenous Therapy

California Code of Regulations

Article 6. Practice of Naturopathic Medicine

§4237.1. Training Requirements for Certification. Intravenous Therapy.

- (a) In order to perform intravenous (IV) therapies, a naturopathic doctor must comply with the following:
- (1) Appropriate certification in basic IV therapies from a provider approved by the Committee as outlined in section 3640.8 of the Code.
 - (2) A recertification is required every five (5) years thereafter.
Recertification must include all of the following:
 - (A) A review of admixtures from initial certification training and all new admixtures that are available manufactured and/or compounded that are chemically independent of any other previously manufactured or compounded agents.
 - (B) Appropriate diagnosis, dosing and infusion times for all admixtures.
 - (C) Safety and known side effects for nutritional IV therapy.
 - (D) Appropriate lab testing prior or during treatment.
 - (3) Certification in cardiopulmonary resuscitation (CPR) is required for all naturopathic doctors performing this therapy.
 - (4) Advanced cardiovascular life support (ACLS) certification is required for all doctors performing this therapy.

b) Proposed language - §4237.2 Training Requirements for
Injection Therapy

California Code of Regulations

Article 6. Practice of Naturopathic Medicine

§4237.2. Training Requirements for Certification. Injection Therapy.

- (a) In order to perform injection therapies, a naturopathic doctor must meet the certification requirements in section 4237.1.
- (b) ACLS certification is required for all doctors performing injection therapies.
- (c) A naturopathic doctor must have additional training for the following advanced injection therapies listed in this section. Recertification for these advanced therapies is required every five (5) years. Supplemental training must be obtained for new techniques, agents, or admixtures as they are introduced to the human market.
 - (1) For the use of ethylene diamine tetra-acetic acid (EDTA), 2,3 dimercaptopropane sulfonate (DMPS), dimercaptosuccinic acid (DMSA), and any other known chelating agents, a naturopathic doctor must have an additional twelve (12) hours of training for IV and oral chelation therapies by a continuing education provider approved by the Committee as outlined in 3635 and 3635.2 of the section.
 - (2) The breakdown of the twelve (12) hours of chelation therapy are as follows:

Chelation Training Content	Hours
Introduction	1.0
EDTA, DMSA, and/or equivalent agent Method of Action (MOA) Route of Administration Toxicology Adverse Reactions	2.5
Osmolarity and pH	0.5
EDTA, DMPS, and/or equivalent agent Indications Benefits Contraindications Value Added Benefits of IV Admixture	2.0
Chelation Patient Qualification Optional Testing Dosage and Frequency of Therapy	1.0
Office Procedures and Documentation	1.0
Patient Care Costs, Management, Case Presentations, Resources	3.0
Certification Exam	1.0
Total Hours	12.0

California Code of Regulations

Article 6. Practice of Naturopathic Medicine

- (3) For the use of platelet rich plasma (PRP) therapy, a naturopathic doctor must complete an additional six (6) hours of instruction, including four (4) hours of lecture and/or discussion and two (2) hours of hands on training in the preparation of PRP.
 - (A) The naturopathic doctor must be compliant with all applicable laws and regulations for handling blood products.
 - (B) Naturopathic doctors must be trained in each route of administration used (i.e., subcutaneous, intradermal, intramuscular, or intraarticular).
- (4) For micro-needling, which involves subcutaneous and intradermal injection therapy, a naturopathic doctor must complete an additional four (4) hours of training in the proper use of a micro-needling pen by a continuing education provider approved by the Committee as outlined in 3635 and 3635.2 of the section.
 - (A) If PRP is used with micro-needling therapy, a naturopathic doctor must meet the training requirement of PRP therapy.
- (5) For the use of ozone oxygen therapy, a naturopathic doctor must complete an additional twelve (12) hours of training by a continuing education provider approved by the Committee as outlined in 3635 and 3635.2 of the section.
 - (A) The treatment of blood, PRP, and saline with ozone gas which is then injected into the vascular system or tissues is allowed.
 - (B) The injection of ozone gas into the soft tissues is allowed.
 - (C) The direct injection of ozone gas into the vascular system is prohibited.
 - (D) Naturopathic doctors must be trained in each route of administration used with ozone therapy, (i.e., subcutaneous, intradermal, intramuscular, intraarticular, or intravenous).

c) Proposed language - §4237.3 Intravenous and Injection
Therapy. Office Requirements

California Code of Regulations

Article 6. Practice of Naturopathic Medicine

§4237.3. Intravenous and Injection Therapy. Office Requirements

- (a) All naturopathic practices that offer intravenous and/or injection therapies, must use appropriate clean and sterile techniques and equipment at all times.
- (b) Compliance with all current state and federal laws, must be in place.
- (c) Compliant and appropriate sharps containers, biohazard containers and waste disposal products and services must be used and adhered to.
- (d) A mobile emergency box or cabinet must be maintained within the office where these therapies are performed, at all times. The kit must contain all appropriate, unexpired products. The emergency kit must include all of the following, but is not limited to:
 - (1) Oxygen tank and flowmeter.
 - (2) Mask, cannula, and tubing.
 - (3) Berman-type oral airway device.
 - (4) Blood pressure cuff.
 - (5) Stethoscope.
 - (6) Additional IV fluids, tubing, and needles.
 - (7) Glucose tabs or equivalent.
 - (8) Gloves, gauze bandages, tape.
 - (9) Required medication to include:
 - (A) Ammonia Salts (smelling salts);
 - (B) Epinephrine, 1:1000 (1 mg per ml) for intramuscular, subcutaneous, and 1:10,000 (0.1 mg per ml) intravenous use;
 - (C) Dextrose, 50% for injectable use;
 - (D) Calcium Gluconate, 1 gram vial or Calcium Chloride, 20% 10 ml pre-fill syringes;
 - (E) Diphenhydramine:
 - I. Adults: 25 – 50 mg q 4-8 hours, not to exceed 400 mg/24 hours.
 - II. Children: 5 mg/kg q 6-8 hours, not to exceed 400 mg/24 hours.
- (e) In addition, the following items are required to be on premises at all times:
 - (1) Emergency automated external defibrillator (AED) ; and
 - (2) Backboard.
- (f) A designated refrigerator with controlled temperature must be onsite for all refrigerated and opened multiuse injectables. The storage of food, blood products or biological materials in the same refrigerator is prohibited. Other injectables and IV solutions that do not require refrigeration must be stored per manufacturer instructions.
- (g) The office must have access to restrooms.
- (h) The office must be accessible to persons with disabilities.

d) Proposed language - §4237.4 Intravenous and Injection Therapy. Staffing Requirements

California Code of Regulations

Article 6. Practice of Naturopathic Medicine

§4237.4. Intravenous and Injection Therapy. Staffing Requirements

- (a) All naturopathic doctors and staff participating in providing patients with IV infusions and/or injection therapies, must have appropriate licensing and/or certifications per sections 4237.1 and 4237.2, respectively.
- (b) There must be at the least one (1) staff member and one (1) naturopathic doctor onsite during IV or injection therapies when there are one (1) to ten (10) patients present. An additional staff member or naturopathic doctor is required for every 5 additional patients. This is a minimum requirement.
- (c) The naturopathic doctor or their staff will obtain written informed consent from the patient prior to the administration of IV or injection therapies.
- (d) Certification in CPR is required for all staff members onsite.
- (e) Naturopathic Assistants must adhere to section 3640.2 of the code.

TAB 4

Review and Approval of 12/16/2019 Meeting
Minutes



**NATUROPATHIC MEDICINE COMMITTEE
IV THERAPY SUBCOMMITTEE
MEETING MINUTES**

December 16, 2019

DRAFT

**MEMBERS
PRESENT:** Dara Thompson, ND, Chair
Virginia Osborne, ND

**MEMBERS
ABSENT:** Vera Singleton, ND

**STAFF
PRESENT:** Rebecca Mitchell, Executive Officer (EO)
Sabina Knight, Esq., Legal Counsel

**MEMBERS OF
THE AUDIENCE:** None

Agenda Item 1 Call to Order/Roll Call/Establishment of a Quorum

Dara Thompson, ND, Chair, IV Therapy Subcommittee of the Naturopathic Medicine Committee (NMC), called the meeting of the IV Therapy Subcommittee to order on December 16, 2019, at 1:18 p.m. A quorum was present and due notice was provided to all interested parties. Member Dr. Singleton was absent with cause.

Agenda Item 2 Public Comment for Items Not on Agenda

There were no public comments for any items not on the agenda to discuss.

**Agenda Item 3 Discussion and Possible Recommendations Regarding
IV Therapy Regulations:**

The sample text (provided in materials) was created by Dr. Thompson and Dr. Osborne. Consultation of specific advanced elements were made by subject matter experts to Dr. Thompson during the research into each therapy.

The sample text was reviewed by Thompson and Osborne. With some small edits to the include "informed consent", removal of specific federal laws and include a statement that "licensee must comply with all federal and state laws".

In the Sample Emergency Kit language, add “thermometer” to the list and add the “not to exceed” information to the children dosage of diphenhydramine.

All members agreed to the changes and tasked EO Mitchell and legal counsel to provide sample regulatory language for the intravenous and injection therapies.

Agenda Item 4 Review and Approval of November 13, 2019 Meeting Minutes:

The Subcommittee reviewed the November 13, 2019 meeting minutes. The minutes were approved as submitted.

Motion – Thompson / Second – Osborne, to approve the 11/13/2019 meeting minutes as submitted. Roll call vote taken, motion carried 2-0-0. (YES – Thompson, Osborne/ NO – none / Abstentions – none).

Agenda Item 5 Establish Future Meeting Dates and Locations

- Send survey out for future meeting date for week of January 20 – 24, 2020.

Agenda Item 6 Agenda Items for Future Meetings

The following are items that were requested to be added to future meetings:

- Sample Language Review

Agenda Item 7 Adjournment

There being no further business or public comment, Dr. Thompson adjourned the meeting at 1:48 p.m.

TAB 5

Establish Future Meeting Dates and Locations

Naturopathic Medicine Committee
Establish Future Meeting Dates and Locations

<i>Dates</i>	<i>Locations</i>
2 nd Quarter NMC Meeting	

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

TAB 6

Agenda Items for Future Meetings

Naturopathic Medicine Committee

Agenda Items for Future Meetings

[illegible]