

# Department of Consumer Affairs



Intravenous (IV) Therapy

Subcommittee Meeting

Monday, December 16, 2019

1:00 p.m. – 2:00 p.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

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# TAB 1

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## Agenda



**Subcommittee  
Members**

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

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

Monday, December 16, 2019  
1:00 PM to 2:00 PM

**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 Recommendations Regarding IV Therapy Regulations:
  - a. Education and Training Requirements
  - b. Certification for IV Therapy: Basic and Advanced practice of IV Therapy
  - c. Safety Requirements
  - d. Use of Ozone, PRP, Micro-needling
4. Review and Possible Approval of Meeting Minutes:
  - a. November 13, 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](http://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 made a request by contacting Rebecca Mitchell, ADA Liaison, at (916) 928-4785 or via email at [Rebecca.Mitchell@dca.ca.gov](mailto: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

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## Public Comments

Name of Public Providing Comment	Comment Presented

## TAB 3

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### Discussion and Possible Recommendations Regarding IV Therapy Regulations



Education and Training

Certification for IV Therapy: Basic and Advanced

## CA IV Committee

1. Safety of Office Intravenous (IV) and Injections Therapy. Any naturopathic doctor performing IV or injections therapies in California must comply with the following rules.
  - a. **Training** - Appropriate certification in Basic IV nutrient therapies from a provider approved by the NMC. A re-certification is required every 5 years. This re-certification will include. - A review of admixtures from initial certification. All new admixtures that are available manufactured and/ or compounded that are chemically independent of any other previously manufactured or compounded agents. Appropriate diagnosis, dosing and infusion times for all admixtures. Safety and known side effects for nutritional IV therapy. Appropriate lab testing prior or during treatment.
  - b. **Emergency medicine** - Certification in CPR is required for all staff members on site. ACLS certification is required for all doctors.
  - c. **Emergency supplies** - There must be an office emergency box or cabinet that is mobile with appropriate in date products - (see addendum for specific contents)
  - d. **Ratio of pt to staff** - At least one staff member in addition to the naturopathic doctor must be on site at all times for 1-10 IV patients. An additional staff member is require for every 5 addition patients - i.e doctor + 2 staff members for 15 patients, doctor + 3 staff members for 20 patients. This is a minimum requirement; there may need to be addition staff based on the complexity of the treatments. This should be determined by the doctor
  - e. **Office space** - The office must provide access to restrooms and access to persons with disabilities
  - f. **Consent** - The naturopathic doctor or her/his staff will obtain written consent from the patient prior to the administration of IV therapy
  - g. **Compliance** - Appropriate clean and sterile techniques and equipment must be used at all times. Compliance with all current state and federal regulations must be in place. This includes OSHA appropriate sharps containers, biohazard containers and waste disposal.
  - h. **Storage** -Designated refrigerator with controlled temperature 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 should be stored per manufacturer instructions.
  - i. **Licensing** - Appropriate licensing and certification of all staff members participating in the IV therapy infusions for patients. Please note that at this time naturopathic medical assistants can not mix IV bags or pushes, start IVs or add medications to an IV.
2. Additional training is required for the following advanced injection therapies. Re-certification for these advanced therapies is required every 5 years. Supplemental

training may also be required for other advanced injection therapies in the future, as new techniques, agents or admixtures are introduced to the human market. The committee may add to these requirements at that time.

1. **Chelation** - IV and oral chelation therapy requires an additional 12 hours of training with a provider approved by the NMC. This is required for the use of EDTA, DMPS, DMSA and any other known chelating agents.
2. **PRP: platelet rich plasma therapy** - PRP requires an additional 6 hours of instruction with 4 hours of lecture/discussion and 2 hours of hands on training in the preparation of PRP. PRP must be prepared using sterile PRP kits or using sterile equipment and a class 5 hood. The use of non-sterile ACD, EDTA or heparin tubes that are intended to be used for phlebotomy is prohibited. In addition, naturopathic doctors must be trained in each route of administration used, i.e. sub Q, intradermal, IM or intrarticular.
3. **Microneedling** - *(This therapy involves subcutaneous and intradermal injection. As such it falls under the scope of naturopathic doctors in California)*. Microneedling requires an additional 4 hours of training in the proper use of a microneedling pen with a provider approved by the NMC. If PRP is used with this therapy separate training in the proper use of PRP is required.
4. **Ozone oxygen therapies** - *(This therapy involves the use of medical oxygen. As such it falls under the scope of naturopathic doctors in California)*. Ozone therapy requires an additional 12 hours of training with a provider approved by the NMC. The treatment of blood, PRP and saline with ozone gas which is then injected into vascular system or tissues is allowed. The injection of ozone gas into the soft tissues is allowed. However, the direct injection of ozone gas into the vascular system is prohibited. As with PRP naturopathic doctors must be trained in each route of administration used, i.e. sub Q, intradermal, IM or intrarticular.

## Sample Chelation Language

IV EDTA of chelation is to be used only for heavy metal detoxification, unless under the auspices of an IRB-approved research protocol. All members agreed that the EDTA subject matter be broadened to include DPMS, DMSA, and/or any equivalent agent.

Prerequisites:

- Maintain a current and valid license to practice naturopathic medicine in California.
- Successful completion of a 25-hour IV therapy course (as approved by the Committee)

Advanced Chelation therapy training should include:

<b>Content</b>	<b>Hours</b>
Introduction	1.0
EDTA, <a href="#">DPMS, DMSA, and/or equivalent agent</a> <a href="#">Method of Action (MOA)</a> <a href="#">Route of Administration</a> Toxicology Adverse Reactions	2.5
Osmolarity and pH	0.5
EDTA, <a href="#">DPMS, DMSA, and/or equivalent agent</a> Indications Benefits Contraindications Value Added Benefits of IV Admixture	<a href="#">2.0</a>
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	<a href="#">1.0</a>
<b>Total Hours</b>	<b>12.0</b>

## Safety Requirements

### Sample Emergency Kit Language

- (a) Any naturopathic practice that provides intravenous (IV) and injection therapy services shall have an emergency kit available. Each emergency kit is required to contain
1. Oxygen tank and flow meter
  2. Mask, cannula, and tubing
  3. 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. Epinephrine, 1:1000 for intramuscular, subcutaneous, and intravenous use
    - b. Dextrose, 50% for injectable use
    - c. Calcium Gluconate or Calcium Chloride, 20% 10 mil pre-fill syringes
    - d. 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 \_\_\_\_?)]
    - e. Ammonia salts (smelling salts)
- (b) Additionally, the following items are required to be within the clinic's premises
1. Emergency AED Defibrillator / Defibrillator
  2. Backboard

Use of Ozone, PRP, Micro-needling



## TAB 4

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### Review and Approval of Meeting Minutes



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

**November 13, 2019**

**DRAFT**

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

**MEMBERS  
ABSENT:** None

**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 November 13, 2019, at 1:04 p.m. A quorum was present and due notice was provided to all interested parties.

**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:**

**a. Education and Training**

Discussed within the Certification for IV Therapy: Basic and Advanced practice of IV Therapy (sec. b. below).

**b. Certification for IV Therapy: Basic and Advanced practice of IV Therapy**

The subcommittee members discussed the training requirements for basic versus advanced practices for IV therapies during this meeting, please see more about this under sec. d, shown below.

### **c. Safety Requirements**

For the practice of IV therapy, all subcommittee members agreed that there must be at least two (2) individuals (one (1) naturopathic doctors (ND), and one (1) naturopathic assistants (NA), and/or one (1) staff member) who are certified in cardiopulmonary resuscitation (CPR).

Dr. Osborne recommends that if a naturopathic medical office offers IV therapy, all medical and non-medical staff should be trained in CPR. In addition, she recommended that the ratios should be one (1) trained ND and one (1) trained medical staff per every ten (10) patients actively receiving IVs. All subcommittee members agreed.

Dr. Osborne shared a sample list of safety items that should be required in order to provide IV therapy. Dr. Osborne stated that there are both required and recommended items on the list. After the Subcommittee reviewed and discussed the list, the following recommendations were added to the IV therapy safety protocol list:

### **Sample Emergency Kit Language**

(a) Any naturopathic practice that provides intravenous (IV) and injection therapy services shall have an emergency kit available. Each emergency kit is required to contain

1. Oxygen tank and flow meter
2. Mask, cannula, and tubing
3. 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. Epinephrine, 1:1000 for intramuscular, subcutaneous, and intravenous use
  - b. Dextrose, 50% for injectable use
  - c. Calcium Gluconate or Calcium Chloride, 20% 10 mil pre-fill syringes
  - d. 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 \_\_\_\_?)]
  - e. Ammonia salts (smelling salts)

(b) Additionally, the following items are required to be within the clinic's premises

1. Emergency AED Defibrillator / Defibrillator
2. Backboard

Members agreed to edit the following from the original list:

- Laryngoscope (remove from list) – Thompson
- Find generic name for “Airways” – per legal opinion
- Backboard and defibrillator is not part of kit but must be on premises – Osborne
- Glucose tabs (add “or equivalent”) – Thompson
- In Sec. b, remove recommendation regarding Rescue Remedy and high-protein snacks, juices, and crackers. This will be added to a best practices section on the Committee’s website. – per legal opinion
- In addition to removing Sec. b, use non-brand name for Rescue Remedy (i.e., herbal flower remedy). – per legal opinion
- Reorder the list to add clarity (i.e., stethoscope and BP cuff should be listed subsequently. – Thompson

In addition to the suggested recommendations, it was also recommended that language pertaining to the use of bulk drugs vs. patient specific prescription drugs be added to the IV therapy regulations and language that “*licensees shall abide by all state and federal pharmacy laws*”. Although, this should be common knowledge, the subcommittee feels that it is important to include the language in the regulations to help further clarify the IV therapy regulations, and to ensure the highest quality of safe naturopathic care is provided. The subcommittee also suggests that the Board of Pharmacy’s (BOP) website address be linked to our website to encourage licensees to use the resources that BOP makes available.

**d. Use of Ozone, PRP, Micro-needling (advanced therapies)**

The subcommittee members agreed that in addition to the basic IV therapy training, advanced training requirements will need to be met in order to perform ozone, platelet-rich plasma (PRP), micro-needling, and chelation therapies.

Dr. Thompson researched the standards of training requirements for each of the above therapies. All members agreed that advanced training courses must meet a certain number of instruction hours in addition to meeting a specific curriculum.

Agreeing mostly with the original recommendations from the 2007 chelation blueprint, the subcommittee proposed that any ND wishing to independently perform IV chelation complete a 12-hour continuing education course, as specified below, in addition to the basic IV therapy course. There was a minor change in the breakdown of hours, with additional hour to be used in instruction and not in the examination time.

In addition, Dr. Osborne suggested using the “method of action” instead of “MOA” and to include the “Route of Administration” just to further clarify.

IV EDTA of chelation is to be used only for heavy metal detoxification, unless under the auspices of an IRB-approved research protocol. All members agreed that the EDTA subject matter be broadened to include DPMS, DMSA, and/or any equivalent agent.

Prerequisites:

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Advanced Chelation therapy training should include:

<b>Content</b>	<b>Hours</b>
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<u>EDTA, DPMS, DMSA, and/or equivalent agent</u> <u>Method of Action (MOA)</u> <u>Route of Administration</u> Toxicology Adverse Reactions	2.5
Osmolarity and pH	0.5
<u>EDTA, DPMS, DMSA, and/or equivalent agent</u> Indications Benefits Contraindications Value Added Benefits of IV Admixture	<u>2.0</u>
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	<u>1.0</u>
<b>Total Hours</b>	<b>12.0</b>

All members agreed to the following:

- Ozone therapy:
  - 12-hour ozone therapy course required
- PRP therapy:
  - Must have basic PRP training (injectable sterile preparations, etc. (6.0 hours)).
  - Each specific route of administration will require additional training specific to that route (scalp injection vs. interarticular injection, etc. additional training hours will be required).
    - Additional hours will be determined after speaking to the subject matter experts on the articular injections.
- Micro-needling therapy:
  - 4 hours of training for micro-needling technique.

In addition, the following should include:

- Instructional hours, and
- Practicum hours
- Extra training for specific area (location of administration)

#### **Agenda Item 4      Review and Approval of Meeting Minutes:**

##### **a) May 6, 2019 Meeting Minutes**

The Subcommittee reviewed the May 6, 2019 meeting minutes. The minutes were approved with amendments.

*Motion* – Thompson / Second – Osborne, to approve the 05/06/2019 meeting minutes as submitted. Roll call vote taken, motion carried 3-0-0. (YES – Thompson, Singleton, Osborne/ NO – none / Abstentions – none).

##### **b) July 15, 2019 Meeting Minutes**

The Subcommittee reviewed the July 15, 2019 meeting minutes. The minutes were approved with amendments.

*Motion* – Thompson / Second – Singleton, to approve the 07/15/2019 meeting minutes as submitted. Roll call vote taken, motion carried 3-0-0. (YES – Thompson, Singleton, Osborne/ NO – none / Abstentions – none).

#### **Agenda Item 5                      Establish Future Meeting Dates and Locations**

- Send survey out for future meeting date

#### **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 1:58 p.m.***

## TAB 5

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Establish Future Meeting Dates and Locations



Naturopathic Medicine Committee  
Establish Future Meeting Dates and Locations

<b><i>Dates</i></b>	<b><i>Locations</i></b>
1 <sup>st</sup> Quarter Full NMC Meeting (Annual meeting)	TUE, JAN 28, 2020

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

# TAB 6

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## Agenda Items for Future Meetings

