

ATTACHMENT 3

Department of Consumer Affairs TITLE 16. NATUROPATHIC MEDICINE COMMITTEE

PROPOSED REGULATORY LANGUAGE IV and Advanced Injection Therapy

Legend:	Added text is indicated with an <u>underline</u> .
	Omitted text is indicated by (* * * *)
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Adopt Section 4237.1 of Article 6 of Division 40 of Title 16 of the California Code of Regulations as follows:

§4237.1. Training Requirements for Intravenous Therapy Course.

- (a) In order to perform intravenous (IV) and/or advanced injection therapies that involve IV administration, a naturopathic doctor must pass a qualifying course on IV therapy from an approved provider.
- (b) A certificate of completion from a course on IV therapy is only good for six (6) years and every six (6) years thereafter a naturopathic doctor must obtain recertification by attending a recertification course taught by a continuing education provider approved by the Committee as outlined in section 3635 and section 3635.2 of the Code that includes the following:
 - (1) 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.
 - (2) Appropriate diagnosis, dosing and infusion times for all admixtures.
 - (3) Safety and known side effects for nutritional IV therapy.
 - (4) Appropriate lab testing prior or during treatment.
- (c) Certification in cardiopulmonary resuscitation (CPR) is required for all naturopathic doctors performing this IV and advanced injection therapy.
- (d) Advanced cardiovascular life support (ACLS) certification is required for all doctors performing IV and advanced injection therapy.

Note: Authority cited: Sections 3622 and 3640.8, Business and Professions Code.
Reference: Sections 3620.1 and 3640.8, Business and Professions Code.

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Adopt Section 4237.2 of Article 6 of Division 40 of Title 16 of the California Code of Regulations as follows:

§4237.2. Training Requirements for Advanced Injection Therapy Courses.

- (a) In order to perform advanced injection therapies that involve IV administration as outlined in subsection (b), a naturopathic doctor must pass a qualifying course as outlined in section 4237.1.
- (b) A naturopathic doctor must have additional training for the following advanced injection therapies listed in this section. Recertification in these advanced therapies is required every six (6) years in addition to the recertification required in section 4237.1. Supplemental training must be obtained for new techniques, agents, or admixtures as they are introduced to the human market.
- (1) For the use of IV Chelating agents, including ethylene diamine tetra-acetic acid (EDTA), 2,3 dimercaptopropane sulfonate (DMPS), and any other known IV chelating agents, a naturopathic doctor must have an additional twelve (12) hours of training for IV chelation therapies from a continuing education provider approved by the Committee as outlined in 3635 and 3635.2 of the Code.
- (2) The IV chelation therapy course must instruct on 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

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- (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 from a continuing education provider approved by the Committee as outlined in 3635 and 3635.2 of the Code.
- (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 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 Code.
- (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 direct 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 allowed route of administration used with ozone therapy, (i.e., subcutaneous, intradermal, intramuscular, intraarticular, or intravenous).

Note: Authority cited: Sections 3622 and 3640.8, Business and Professions Code.

Reference: Sections 3620.1 and 3640.8, Business and Professions Code.

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Adopt Section 4237.3 of Article 6 of Division 40 of Title 16 of the California Code of Regulations as follows:

§4237.3. Intravenous and Advanced Injection Therapy that Involve IV Administration. Office Requirements

- (a) All naturopathic practices that offer intravenous and/or injection therapies outlined in Section 4237.1 and 4237.2, 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) Thermometer
 - (7) Additional IV fluids, tubing, and needles
 - (8) Glucose tabs or equivalent
 - (9) Gloves, gauze bandages, tape
 - (10) 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; and
 - (E) Diphenhydramine
- (e) In addition, the following items are required to be on premises at all times:
 - (1) Emergency defibrillator; and
 - (2) Backboard.
- (f) A designated refrigerator with controlled temperature must be on-site for all injectables requiring refrigeration. 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 that are easily monitored by staff.

Note: Authority cited: Sections 3622 and 3640.8, Business and Professions Code.

Reference: Sections 3620.1 and 3640.8, Business and Professions Code.

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§4237.4. Intravenous and Advanced Injection Therapy that Involve IV Administration. Staffing Requirements

- (a) All naturopathic doctors and staff participating in providing patients with IV infusions and/or the injection therapies listed in Section 4237.2 (b), must have passed the appropriate qualifying courses per sections 4237.1 and 4237.2, respectively.
- (b) There must be at the least two (2) personnel, one (1) which must be a naturopathic doctor, on-site 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 five (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 on-site.
- (e) Naturopathic Assistants must adhere to section 3640.2 of the Code.

Note: Authority cited: Sections 3622 and 3640.8 Business and Professions Code.

Reference: Sections 3620.1 and 3640.8, Business and Professions Code.

§4237.5 Intravenous Therapy Course Provider Approval.

(a) An individual or business applying for Committee approval as an intravenous (IV) therapy course provider shall submit a completed application to the Committee that shall include the following:

- (1) Identifying information for the name, location and contact for the course provider.
- (2) A course outline showing how the material required by section 3640.8 of the Code and sections 4237.1 will be covered.
- (3) A description of:
 - (A) the methods of instruction,
 - (B) the total number of hours in the course and the course location,
 - (C) the methods of evaluation for both instructor evaluation of student achievement of course objectives and for student evaluation of course content and course instructor,
 - (D) the course instructor's qualifications
 - (E) a commitment that the provider shall only issue a certificate of completion to a participant upon the participant's passage of a summative assessment of the participant's understanding of the IV therapy coursework. The assessment shall have a minimum cumulative passing score of at least eighty percent (80%).
 - (F) a certification under penalty of perjury that the information provided in the report is true and correct.

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(b) The Committee will review the application and decide whether or not to approve to the provider. A provider will not be approved for more than a two-year period. Following approval by the Committee within each two-year period, the provider may offer an unlimited number of IV therapy courses.

(c) An approved provider shall have a written and published policy, available on request, which provides information on:

(1) refunds in the case of non-attendance

(2) time period for return of fees

(3) notification if course is cancelled

(d) The approved provider is required to accept full responsibility for each and every course, including but not limited to recordkeeping, advertising course content, issuance of certificates, and instructor qualifications.

(e) Approved providers shall keep the following records for a period of six (6) years:

(1) records of dates and places each course is given,

(2) instructor curriculum vitae or resumes

(3) names and license numbers of naturopathic doctors who take the IV therapy course and a record of any certificate issued to them.

(f) Provider approval is non-transferable.

(g) Approved providers must notify the Committee within thirty (30) days of any changes in information that was submitted on the most recent approved application to the Committee.

(h) Approval of an IV therapy course provider may be withdrawn if the Committee later discovers misrepresentation in an advertisement or in any information required by the Committee in accordance with this section.

Note: Authority cited: Sections 3622 and 3640.8, Business and Professions Code.
Reference: Sections 3620.1 and 3640.8, Business and Professions Code.