

## **FORMULARY COMMITTEE RECOMMENDATIONS**

There are two main factors to be considered when making recommendations for naturopathic medicine formulary laws. First, it is paramount that the act of prescribing or IV administration be done safely by a competently trained ND. Secondly, the substance being administered must be prepared in a way to provide for absolute patient safety. Both of these factors were considered by the Committee in many arduous discussions in order to prepare the recommendations provided in this report.

### **Recommendation # 1—Prescribing Laws Need to Be Clarified.**

It was the intent of the sponsors of SB 907, and the intent of the clarification to Section 3640(c)(1) in AB 302 that NDs are to be recognized as independent intravenous and intramuscular prescribers for the substances listed in Section 3640(c)(1)--food, extracts of food, nutraceuticals, vitamins, amino acids, minerals, enzymes, botanicals and their extracts, botanical medicines, homeopathic medicines, all dietary supplements and nonprescription drugs as defined by the federal Food, Drug, and Cosmetic Act. The Committee recommends that statutory and/or regulatory changes be made to effectuate this clarification in the pharmacy laws and the Act.

### **Recommendation # 2—Regulation of the Ocular Route.**

Section 3627 requires the Bureau to make recommendations regarding the required supervision and protocols for utilization of the ocular route of prescription drug administration. Section 4234(d) of Division 40 of Title 16 of the California Code of Regulations specifies that an ND may only use the ocular route of administration if he or she is clinically competent in that area. Clinical competence is defined as possessing and exercising the degree of learning, skill, care and experience ordinarily possessed and exercised by a member of the appropriate discipline in clinical practice. Use of the ocular route is limited by the authorized formulary (see Ophthalmic Agents in Recommendation #6). The Committee has determined that further regulation of this route is not necessary.

### **Recommendation # 3—IV Therapy Blueprint.**

It is the intent of the Committee to protect the health and welfare of California consumers by ensuring the training and competency of NDs who use the intravenous route of administration. The Committee recommends that the Bureau implement a regulatory change that would require any ND who wishes to utilize the intravenous route of administration to complete a 25-hour continuing education course in IV administration, as specified.

#### **Course Requirements:**

- Courses are to be pre-approved by the Bureau, and are to contain a minimum of 25 contact hours. Of the 25 hours, 14 hours shall be identified as practicum.

#### **Course Outline**

- I. Introduction, rationale and history
- II. Lab evaluation, pt fluid status, CV status, kidney function.
- III. IV fluids, including mOsm calculations, diluents, admixtures, definitions pertinent to IV therapeutics,
- IV. Equipment, supplies.
- V. Sterile techniques, admixing.
- VI. Vein/site selection, site preparation, insertion techniques
- VII. Complications with therapies, errors and adverse reactions, reporting errors to appropriate agencies, error prevention, follow-up with patient complications, FDA Watch.
- VIII. Emergency protocols, management and referral.
- IX. Pharmacology, indications, preparation, adverse reactions, nutrient/drug interactions and administration of IV vitamins, minerals, electrolytes, amino acids, botanicals, biologicals, including DMPS.
- X. Charting, standards of care, OSHA, certification standards
- XI. Catheters/pic lines: standard of care for approach and management, co-management with medical providers.
- XII. Practicum
  - a. Observations of IV set up and administration—must observe at least 10.
  - b. Successful completion of IV set up, administration and management—must complete at least 10.
- XIII. Exam  
Successful completion (70% or greater) of a minimum of 50 questions (10% or more of the questions must have direct content to California formulary categories).

### **Recommendation # 4—IV Formulary.**

It is the recommendation of the Committee that NDs who have successfully completed an approved IV continuing education course as specified above be able to independently administer the following substances via the IV route of administration.

**I. Category: Amino Acids and Glutathione**

**II. Category: Vitamins**

**III. Category: Minerals**

**IV. Category: Electrolytes, Sugars, and Diluents**

**V. Category: Chelating Agents:**

⇒ Substances:

1. DMPS	2. EDTA
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**VI.** Any substance that may be prescribed or furnished by an ND which is part of an Institutional Review Board (IRB) approved study.

## Recommendation # 5—Chelation Blueprint.

It is recommended that any ND wishing to independently perform IV chelation complete a 12-hour continuing education course, as specified below, in addition to the IV therapy course. IV EDTA of chelation is to be used only for heavy metal detoxification, unless under the auspices of an IRB-approved research protocol.

### CHELATION BLUEPRINT

#### Pre-requisites

- ✓ Maintain a current and valid license to practice naturopathic medicine in California.
- ✓ Successful completion of the 25-hour IV therapy course.

Content	Hours
Introduction	1.0
EDTA MOA Toxicology Adverse Reactions	2.5
Osmolarity and pH	0.5
EDTA Indications Benefits Contraindications Value Added Benefits of IV Admixture	1.0
Chelation Patient Qualification Optional testing Dosage and Frequency of Therapy	1.0
Office Procedures and Documentations	1.0
Patient Care Costs, Management, Case Presentations, Resources	3.0
Certification Exam	2.0
<b>Total Hours</b>	<b>12.0</b>

## **Recommendation # 6—Pharmaceutical Formulary.**

It is recommended that changes be made to statutory law and subsequently to the Bureau's regulations to allow NDs to be able to independently prescribe, without supervision or protocol, from the formulary below (in addition to what is currently allowed by Section 3640.7). It is recommended that this formulary be included and maintained in the California Code of Regulations, rather than in statute. It is further recommended that a statutory change be made in order to require the Bureau in consultation with the Committee and the Naturopathic Advisory Council to review and update the naturopathic formulary on an annual basis. Changes to the formulary by the Bureau would be recommended by the Committee and approved by the Naturopathic Advisory Council.

### **ANTIBIOTICS**

Amebecides

Antifungal agents

Anthelmintics

Antimalarial preparations (includes artemesin, derived from *Artemesia annua*)

Antiprotozoal agents

Antiviral agents

Bacitracin

Cephalosporins and related antibiotics

Fluroquinolones

Macrolides

Nitrofurantoin

Metronidazole

Neomycin

Nitrofurans

Penicillins

Quinalones

Sulfonamides

Tetracyclines

### **PAIN CONTROL AGENTS**

Salicylates

NSAIDS

Opioid Analgesic Combinations - Schedules III, IV, and V only

## **DERMATOLOGICALS**

- Anti-fungals - topical
- Anti-infectives, topical
- Anti-inflammatory agents
- Anti-psoriatic agents
  - excluding methotrexate
- Antihistamine preparations, topical
- Antiseborrheic products
- Arnica
- Counterirritants
- Destructive agents
- Dressings and granules
- Drying agents
- Eflornithine HCl
- Enzyme preparations
- Immunomodulators, topical
- Irrigating solutions
- Keratolytic agents
- Local anesthetics
  - Topical
  - IM and SQ Bupivacaine, Lidocaine, and Procaine
  - IM and SQ Epinephrine
- Minoxidil
- Photochemotherapy
- Pigment agents
- Protectants
- Pyrithione zinc
- Retinoids — dermatologic (oral)
- Rexinoids
- Scabicides/pediculicides
- Topical steroids

## **OPHTHALMIC AGENTS**

- Antibiotics
- Mast cell stabilizers
- Ophthalmic antihistamines
- Otic antibiotics and combination preparations

## **RESPIRATORY AGENTS**

- Bronchodilators
- Expectorants
- Antihistamines
- Antitussives and combined antitussives
- Bronchodilators
- Leukotriene formation inhibitors
- Leukotriene receptor antagonists

## **GASTROINTESTINAL AGENTS**

Proton pump inhibitors  
Antidiarrheals  
Gallstone Solubilizing Agents  
H. pylori agents

## **CARDIOVASCULAR AGENTS**

Anti-hyperlipidemic agents

## **RENAL AND GENITOURINARY AGENTS**

Vaginal Preparations

## **DIAGNOSTIC AGENTS**

In vitro Diagnostics Aids  
In vivo Diagnostic Biologicals

## **VACCINES**

## **ANTI-DIABETIC AGENTS**

## **IV FORMULARY**

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**II. Category: Vitamins**

**III. Category: Minerals**

**IV. Category: Electrolytes, Sugars, and Diluents**

**V. Category: Chelating Agents:**

⇒ Substances:

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