FORMULARY COMMITTEE
FINDINGS & 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, rational 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

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
Total Hours	**12.0**

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
Antihelminthics
Antimalarial preparations (includes artemesin, derived from Artemesia annua)
Antiprotozoal agents
Antiviral agents
Bacitracin
Cephalosporins and related antibiotics
Fluroquinolones
Macrolides
Nitrofurantoins
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 HCI
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

I. Category: Amino Acids and Glutathione

II. Category: Vitamins

III. Category: Minerals

IV. Category: Electrolytes, Sugars, and Diluents

V. Category: Chelating Agents:

⇒ Substances:

3. DMPS	4. EDTA

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