Date of Hearing: June 19, 2012

ASSEMBLY COMMITTEE ON BUSINESS, PROFESSIONS AND CONSUMER PROTECTION
Mary Hayashi, Chair
SB 1446 (Negrete McLeod) – As Amended: June 12, 2012

SENATE VOTE: 37-0

SUBJECT: Naturopathic doctors.

SUMMARY: Allows naturopathic doctors (NDs) to independently prescribe any substances that require a prescription because they are injectable solutions administered by intramuscular (IM) or intravenous (IV) routes, and requires NDs to complete a qualifying course in order to administer IV therapy. Specifically, this bill:

1) Allows NDs to independently prescribe any substances that require a prescription because they are injectable solutions administered by IM or IV routes, including vitamins, minerals, amino acids and glutathione, 2,3-Dimercapto-1-propanesulfonic acid (DMPS), ethylenediaminetetraacetic acid (EDTA), botanicals and their extracts, homeopathic medicines, electrolytes, sugars, and diluents.

2) Requires an ND, in order to qualify to administer IV therapy in his or her practice pursuant to existing law, to demonstrate that he or she has a current California ND license and has completed a qualifying course on IV therapy from a course provider approved by the Naturopathic Medicine Committee (NMC).

3) Requires the qualifying course to consist of a minimum of 25 classroom hours on IV administration through injection of applicable naturopathic formulary substances, of which at least 14 classroom hours shall be identified as practicum. At a minimum, the qualifying course shall have covered all of the following topics:

    a) Evaluation of laboratory results, including, but not limited to, the fluid status, cardiovascular status, and kidney function of the patient;

    b) The use of IV fluids, including, but not limited to, osmolarity calculations, diluents, and admixtures pertinent to IV therapeutics;

    c) Sterile techniques and admixing;

    d) Vein and site selection, site preparation, and insertion techniques;

    e) Complications with therapies, nutrient and drug interactions, errors and adverse reactions, reporting errors to appropriate agencies, error prevention, and follow-up with patient complications;

    f) Emergency protocols, management, and referral;

g) Pharmacology, indications, preparation, and IV administration of vitamins, minerals, amino acids and glutathione, 2,3-Dimercapto-1-propanesulfonic acid (DMPS), ethylenediaminetetraacetic acid (EDTA), botanicals and their extracts, homeopathic medicines, electrolytes, sugars, and diluents;

h) Practicum, including, but not limited to, the following:

i) Observation of at least 10 IV setups, including administration and management;

ii) Successful completion of at least 10 IV setups, including administration and management; and,

i) Successful completion of an examination with 70% or greater correct answers to a minimum of 50 questions, where 10% or more of the questions have direct content to the California formulary.

4) Defines, for the purposes of the qualifying course required by this bill, one classroom hour as 50 minutes out of each 60-minute segment, which may include time devoted to examinations. No credit shall be granted for distance education, including, but not limited to, correspondence courses, Internet courses, or video or remote television offerings.

5) Allows the NMC to establish regulations regarding IV administration that are consistent with the education and training of an ND.

6) Makes conforming and technical changes.

EXISTING LAW

1) Provides, under the Naturopathic Doctors Act (ND Act) for the licensure and regulation of NDs by the NMC under the Osteopathic Medical Board (OMB) of California.

2) Authorizes an ND to perform various tasks, including dispensing, administering, ordering, and prescribing specified substances, as defined by the federal Food, Drug, and Cosmetic Act (FDCA), including food, extracts of food, nutraceuticals, vitamins, amino acids, minerals, enzymes, botanicals and their extracts, botanical medicines, homeopathic medicines, all dietary supplements and nonprescription drugs a defined by the FDCA;

3) Authorizes NDs to use specified routes of administration, including oral, nasal, auricular, ocular, rectal, vaginal, transdermal, intradermal, subcutaneous, IV and IM.

4) Authorizes the NMC to establish regulations regarding ocular or IV routes of administration that are consistent with the education and training of an ND.

5) Authorizes NDs to independently prescribe epinephrine to treat anaphylaxis, and natural and synthetic hormones.

6) Authorizes NDs to furnish or order drugs including Schedule III to V controlled substances under the supervision of a physician.

7) Specifies, under the FDCA, that a drug, including a homeopathic drug, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug, and may be dispensed only upon an oral or written prescription of a practitioner licensed to administer such drug.

FISCAL EFFECT: Unknown

COMMENTS:

Purpose of this bill. According to the author, "SB1446 will clarify existing law for NDs pertaining to the prescribing and administration of non-prescription substances that become prescription substances solely depending on the route of administration, i.e. vitamins through IV administration.

"Currently, the ND Act allows doctors to administer vitamins and minerals orally and intravenously. However, there is conflicting pharmaceutical law that states any substance administered intravenously must be accompanied by a prescription."

Background. Naturopathic medicine includes the combination of a variety of natural medicines and treatments. NDs practice integrative medicine and are primary health care providers who are clinically trained in both natural and conventional approaches to medicine. NDs also write prescriptions for pharmaceuticals and refer patients to conventional physicians and specialists as needed. NDs are also permitted to administer substances via various routes of administration.

In 2003, California became the 13th state to recognize naturopathic medicine and license NDs. The NMC, which is under the OMB, licenses and regulates NDs. Over 500 ND licenses have been issued in California to date. To be eligible for licensure in California, an applicant must graduate from one of six approved naturopathic medical schools accredited by the Council on Naturopathic Medical Education. An applicant is also required to pass a standardized licensing examination used in all states that license NDs, the Naturopathic Physicians Licensing Examination. NDs take board examinations after two and four years. NDs have limited opportunities to complete hospital residencies, but perform at least 1500 hours of clinical rotations at clinics and private doctors' offices during their education program.

The scope of practice for NDs include diagnosis and treatment of patients and the authority to order lab tests and prescribe most drugs, subject to supervision of a medical or osteopathic physician. NDs may perform minor procedures, such as treating lacerations and removing moles and growths. In 11 states, NDs are also permitted to administer substances via IV and IM routes of administration.

The term nutraceutical generally means a product isolated or purified from foods, and generally sold in medicinal forms that reportedly provide health and medical benefits, including the prevention and treatment of disease. Such products may range from isolated nutrients, dietary supplements, genetically engineered foods, herbal products and processed foods such as cereals, soups, and beverages. Nutraceutical foods are not subject to the same testing and regulations as pharmaceutical drugs.

Depending on the substance and the patient, an IV or IM injection may be preferable to other routes of administration. Many substances have more immediate onset of action when administered via IV or IM.

As with any medical procedure, there are risks with utilizing IV and IM routes. If not trained properly, the practitioner may cause nerve damage when administering substances via IM. Site selection is also important because the effect of the medication can be enhanced or diminished depending on the site used. In terms of IV administration, infection is the biggest risk because the skin has been broken, giving bacteria access to the body. In most cases, infection is localized, appearing only at the IV site. However, bacteria can spread throughout the bloodstream. Other risks include embolism, caused by blood clots or air bubbles. While potentially life-threatening, this occurs infrequently.

The FDCA specifies which drugs must be labeled as prescription only:

"A drug intended for use by man which (A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (B) is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug; shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale."

According to the sponsor, the Legislative Counsel provided a legal background on this issue citing case law and concluding, "Whether a drug requires a prescription is often determined by the (Food and Drug Administration) under the new drug application process. Injectable vitamins, because of the method of their use, and certain high dosages of vitamins, because of their toxicity, may require a prescription under (the FDCA)."

The ND Act specifies the routes of administration that an ND may utilize:

"An ND may utilize routes of administration that include oral, nasal, auricular, ocular, rectal, vaginal, transdermal, intradermal, subcutaneous, IV and IM."

However, the allowance for NDs to utilize these routes of administration for nutritional substances is not mentioned in the independent formulary section of the ND Act. It only indicates that an ND may furnish and order drugs in accordance with standardized procedures or protocols developed by the ND and the supervising physician and surgeon:

"Drugs furnished or ordered by a naturopathic doctor may include Schedule III through Schedule V controlled substances under the California Uniform Controlled Substances Act…of the Health and Safety Code and shall be further limited to those drugs agreed upon by the ND and physician and surgeon as specified in the standardized procedure."

The inconsistency between the ND Act and the FDCA, in regards to prescription-only substances, has led to confusion between California NDs and pharmacists. Some pharmacies interpret the ND Act as permitting an ND to order injectable substances intended to be administered via IV and IM routes. However, other pharmacies abide by the FDCA, which specifies that substances become prescriptions once they are injected, and refuse to fill prescriptions from NDs for injectable substances.

Support. The California Naturopathic Doctors Association writes, "SB1446 would clarify the original intent of the ND Act by specifying that naturopathic doctors may independently prescribe substances (such as vitamins, minerals and amino acids) that would not ordinarily require a prescription except that they become a 'drug' because of the route of administration (IM or IV). SB1446 does not alter the scope of practice for naturopathic doctors; it simply clarifies the original statute. This would remove any confusion over the ability of a naturopathic doctor to best serve patients in the safest most effective manner possible…

"NDs are well trained in the use of nutritional IV therapy. Naturopathic medical schools require 30 hours of live instruction, of which at least 14 are hands-on. This is more instruction than is provided in any conventional medical school. NDs also perform IVs during clinical rotations in medical school. Many MDs and (osteopathic physicians) who perform nutritional IV therapy in their practices were taught by NDs. Research studies have shown nutritional IV therapies to be safe and effective for a variety of conditions."

Opposition. The Osteopathic Physicians and Surgeons of California (OPSC) states, "OPSC is concerned that patients could be placed in significant danger if this bill is approved in its current form. Although it sounds rather innocuous to administer natural products, any substance in concentrated doses can cause severe reactions, including potentially fatal conditions. Intravenous administration does not allow the body's natural filters, such as the liver and kidneys, to perform their role in protecting against harmful contraindications.

"OPSC is concerned that NDs do not have sufficient training and/or experience to recognize when a patient has experienced a contraindication from excessive product administration or an understanding of appropriate treatment for these cases."

Previous legislation.

SB 667 (Runner) of 2011 allows NDs to independently dispense, furnish, administer and order epinephrine and natural and synthetic hormones, and to independently dispense, furnish, administer, order, and prescribe vitamins, minerals, and nonprescription drugs, among other substances, using various specified routes of administration. This bill was held in Senate Business, Professions and Economic Development Committee.

AB 302 (Committee on Business and Professions), Chapter 506, Statutes of 2005, makes a number of changes to the authority of NDs to furnish and prescribe dangerous drugs, clarifying that medications provided by NDs may be provided through various routes of administration, and the circumstances under which a ND may furnish or order drugs under the oversight of a supervising physician and surgeon; and, requires NDs to function pursuant to standardized procedures or protocols, as specified.

SB 907 (Burton), Chapter 485, Statutes of 2003, establishes the ND Act, creates the Bureau of Naturopathic Medicine within the Department of Consumer Affairs, establishes criteria for the licensure and regulation of NDs, and establishes a scope of practice for the profession.

REGISTERED SUPPORT / OPPOSITION:

Support

California Naturopathic Doctors Association (sponsor)
Naturopathic Medicine Committee
Numerous individuals

Opposition

American Osteopathic Association
California Medical Association
California Podiatric Medical Association
Osteopathic Physicians and Surgeons of California

Analysis Prepared by: Angela Mapp / B.,P. & C.P. / (916) 319-3301