
**SENATE COMMITTEE ON
BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT**
Senator Jerry Hill, Chair
2015 - 2016 Regular

Bill No:	SB 538	Hearing Date:	April 27, 2015
Author:	Block		
Version:	April 16, 2015		
Urgency:	No	Fiscal:	Yes
Consultant:	Sarah Huchel		

Subject: Naturopathic doctors.

SUMMARY: Expands the scope of practice for a naturopathic doctor, including allowing a naturopathic doctor to prescribe certain drugs without physician supervision and perform minor procedures.

Existing law:

- 1) Establishes the Naturopathic Medicine Committee (Committee) within the Osteopathic Medical Board to enforce and administer the Naturopathic Doctors Act (Act). (Business and Professions Code (BPC) §§ 3612 and 3620)
- 2) Authorizes a naturopathic doctor (ND) to order and perform physical and laboratory examinations for diagnostic purposes, including, but not limited to, phlebotomy, clinical laboratory tests, official examinations, and physiological function tests. (BPC § 3640 (a))
- 3) Authorizes an ND to order diagnostic imaging studies, including X-ray, ultrasound, mammogram, bone densitometry, and others, consistent with naturopathic training as determined by the Committee, but requires the ND to refer the studies to an appropriately licensed health care professional to conduct the study and interpret the results. (BPC § 3640 (b))
- 4) Authorizes an ND to utilize routes of administration that include oral, nasal, auricular, ocular, rectal, vaginal, transdermal, intradermal, subcutaneous, intravenous, and intramuscular. (BPC § 3640 (c))
- 5) Authorizes an ND to repair and care for superficial lacerations and abrasions, except suturing. (BPC § 3640 (c)(5))
- 6) Requires an ND to furnish or order drugs (including Schedule III – V) in accordance with standardized procedures or protocols developed by the naturopathic doctor and his or her supervising physician and surgeon. (BPC § 3640.5 (a))
- 7) Requires the standardized procedure or protocol covering the furnishing of drugs to specify which drugs may be furnished or ordered under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the ND's competence, including peer review, and review of the provisions of the standardized procedure. (BPC § 3640.5 (d))

- 8) Requires Schedule III drugs to be furnished or ordered by an ND in accordance with a patient-specific protocol approved by the treating or supervising physician. (BPC § 3640.5 (f))
- 9) Prohibits an ND from performing any surgical procedure. (BPC § 3642 (f))
- 10) Allows an ND to practice naturopathic childbirth attendance after certification. (BPC 3651)

This bill:

- 1) Authorizes an ND to order diagnostic imaging studies “consistent with the practice of naturopathic medicine,” rather than only those determined appropriate by the Committee.
- 2) Clarifies that an ND may order, provide, or furnish devices consistent with the naturopathic training as determined by the Committee.
- 3) Authorizes an ND to utilize the cervix as a route of administration.
- 4) Authorizes an ND to perform operative procedures relative to superficial lacerations, superficial clinically benign lesions less than one centimeter and not located on the face, and superficial abrasions.
- 5) Authorizes an ND to use topical and parenteral use of substances consistent with the practice of naturopathic medicine in accordance with rules established by the Committee.
- 6) Authorizes an ND to obtain samples of superficial human tissue by means of shave, punch, or excisional biopsy consistent with the practice of naturopathic medicine.
- 7) Prohibits an ND from any procedures using general or spinal anesthesia, sclerotherapy, or procedures involving the eye.
- 8) Defines “parenteral therapy” to mean the administration of substances by means other than through the gastrointestinal tract, including intravenous, subcutaneous, intramuscular, and other areas of the body, excluding the ventral and dorsal body cavities.
- 9) Authorizes an ND to prescribe, administer, or order Schedule IV, V, and unclassified drugs labeled “for prescription only,” except chemotherapeutics, without physician supervision.
- 10) Requires an ND to be subject to peer review reporting provisions.

FISCAL EFFECT: Unknown. This bill has been keyed “fiscal” by Legislative Counsel.

COMMENTS:

1. **Purpose.** This bill is sponsored by the California Naturopathic Doctors Association. According to the Author's office, this bill expands the scope of practice for an ND as follows: allows an ND to prescribe legend and Schedule III-V drugs without physician supervision or pursuant to a standardized protocol; expands the types of diagnostic procedures in an ND's practice and allows an ND to review and interpret the results; allows an ND to study and interpret the results of diagnostic imaging studies; expands the types of "minor procedures" an ND may perform.
2. **Naturopathic Medicine.** According to the Committee, Naturopathic medicine is a distinct and comprehensive system of primary health care that uses natural methods and substances to support and stimulate the body's self-healing process. It is distinguished by the principles on which its practice is based. These principles include:
 - a) The Healing Power of Nature: NDs trust in the body's inherent wisdom to heal itself.
 - b) Identify and Treat the Cause: Look beyond the symptoms to effectively address the underlying cause(s) of illness.
 - c) First Do No Harm: Seek to utilize the most natural, least invasive and least toxic therapies first.
 - d) Doctor as Teacher: The primary role of an ND is a teacher who educates and encourages people to take responsibility for their own health and to take steps to achieve and maintain optimal health.
 - e) Treat the Whole Person: Total health includes physical, emotional, mental, genetic, environmental, social, spiritual, and other factors.
 - f) Prevention: Encourage and emphasize disease prevention and focus on promoting health and wellness.

Naturopathic medicine includes the combination of a variety of natural medicines and treatments. NDs are clinically trained in both natural and conventional approaches to medicine and can prescribe all natural and synthetic hormones, epinephrine, and vitamins, minerals, and amino acids independent of physician supervision. California NDs complete 72 pharmacology course hours in school and are required to complete a minimum of 20 hours of pharmacotherapeutic training every two years as part of their 60 hour continuing education requirement.

NDs attend four year, graduate-level, accredited naturopathic medical schools, are trained as primary care providers, and take a national, standardized licensing examination. 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. California is one of 17 states that license NDs, and over 500 ND licenses have been issued to date. There is one naturopathic medicine school in California, located in San Diego.

3. **Naturopathic and Allopathic Medicine.** While NDs report that they are trained as primary care providers, the National Institute of Health (NIH) considers naturopathy (which includes the practice by naturopathic doctors) complimentary medicine. It cautions that “the complex treatment approaches that naturopathic [doctors] often use are challenging to study, and little scientific evidence is currently available on overall effectiveness. Related research is under way but is in the early stages.”

NIH states that:

- Naturopathy is not a complete substitute for conventional care. Relying exclusively on naturopathic treatments and avoiding conventional medical care may be harmful or, in some circumstances have serious health consequences.
- Some beliefs and approaches of naturopathic practitioners are not consistent with conventional medicine, and their safety may not be supported by scientific evidence.

4. **Changes to Furnishing Authority of a Naturopathic Doctor.** Current law allows an ND to furnish or order legend drugs and Schedule III – V and drugs in accordance with standardized procedures or protocols developed by the naturopathic doctor and his or her supervising physician and surgeon. A physician may supervise up to four NDs at a time.

- a) **Drug classifications.** Drugs, substances, and certain chemicals used to make drugs are classified into five schedules depending upon the drug’s acceptable medical use and the drug’s abuse or dependency potential. Schedule I is considered the most dangerous class and Schedule V represents the least concerning of the Scheduled drugs.

Schedule IV drugs include the mild narcotics, depressants, stimulants, and tranquilizers. Drugs such as Xanax, Ambien, Tramadol, and Valium are in this group. Schedule V drugs consist primarily of preparations containing limited quantities of certain narcotic and stimulant drugs, and include cough syrups with codeine, Lyrica, and Lomotil.

“Legend” drugs are controlled substances but have even less potential for abuse than Schedule V drugs. Antibiotics and insulin are considered legend drugs.

- b) **Committee recommendation to remove supervision.** Current law establishes a Naturopathic Formulary Advisory Subcommittee (Subcommittee) to review naturopathic education, training, and practice and make specific recommendations regarding prescribing, ordering, furnishing authority, and appropriate supervision protocols. The Subcommittee is composed of an equal number of representatives from the clinical and academic settings of physicians and surgeons, pharmacists, and naturopathic doctors. The Subcommittee presented its initial report in 2007.

This report found that there were a limited number of physicians who had training in naturopathic philosophy or practice or who have had the extensive clinical

experience in naturopathic modalities to make them appropriate supervisors for NDs, and the few physicians who were willing and well-trained for ND supervision had difficulty getting malpractice coverage for supervision. The Committee reported concerns from both physicians who had difficulty getting malpractice insurance and NDs who had difficulty finding supervision. This was frustrating for practitioners, as the Subcommittee noted that “malpractice companies routinely insure MDs who supervise other medical professionals such as nurse practitioners and physician assistants, [who] have a lesser entry-level training and education requirement than NDs.” The Subcommittee concluded “the supervision provision is untenable,” but at that point did not recommend independent prescribing privileges.

On January 1, 2014, the Subcommittee reported to the Committee that it unanimously agreed to support elimination of physician supervision and indicated:

Since the original report we have had almost another 7 years of experience with the public receiving Naturopathic medical care in the state of California. The current scope does not put any restrictions on medications prescribed other than those listed in statute (exclusion of schedule 1 & 2) or those agreed upon between the MD/NO in their supervision agreement. We have seen in the last years an excellent safety record with no reports of patient harm or disciplinary action. Elimination of the MD supervision would remove barriers to access to care for patients of NDs unable to secure a supervising MD. The previous formulary report discussed NDs who are having difficulty finding an MD supervisor and MDs experiencing difficulty in securing malpractice coverage to do the supervision. They [the previous Subcommittee] concluded the supervision provision is untenable. [Physician] supervision should be eliminated.

This bill is more restrictive than the Subcommittee recommended, and will allow an ND to furnish only Schedule IV-V drugs and legend drugs, except chemotherapeutics, without physician supervision or pursuant to standardized procedures or protocols.

- 5. Expanded Minor Procedures Would Be Allowed.** Current law authorizes an ND to provide repair and care incidental to superficial lacerations and abrasions, except suturing, and permits an ND to remove foreign bodies located in the superficial tissues.

The Committee convened an advisory group in 2007 consisting of two NDs, two physicians, and one attorney to review whether it would be appropriate to expand the procedures permitted in current law. After a review of the training, education, and practice of NDs, the advisory group reached consensus that an ND should be allowed to perform the following four additional procedures: 1) prescribe and administer local anesthetic solutions, their adjuncts and diluents; 2) removal of clinically benign skin lesions; 3) repair of skin

lacerations, including suturing; and 4) incision and drainage of abscess/trephination of subungual hematoma.

This bill largely tracks these recommendations, but puts greater restrictions on an ND to remove lesions. This bill would specify that an ND may perform operative procedures relative to superficial clinically benign lesions less than one centimeter and not located on the face. It would also permit an ND to obtain samples of tissue by shave, punch, or excisional biopsy, and utilize the cervix as a route of administration, which would clarify an ND's ability to administer common birth control devices.

6. **Sunset Review of the Committee.** The Committee underwent a Sunset Review in 2013 at which time the Senate Business, Professions, and Economic Development (BPED) Committee expressed concern about the Committee's abilities to handle administrative concerns and enforcement activities. It was recommended that the Committee establish disciplinary guidelines, update their strategic plan that expired in 2012, and report to the Legislature by January 1, 2014 on any progress in meeting its goals and objectives. Until progress occurs, it was recommended that there be no scope expansion for NDs.

A new Executive Officer (EO) joined the Committee after 2014, and has shown substantial leadership in refocusing the Committee's efforts. While disciplinary guidelines have not yet been passed, they are in draft form and the EO has assured this Committee that the guidelines and a revised Strategic Plan will be in effect in the next few months. The EO has hired additional staff and reports substantial compliance with the 2013 Sunset concerns.

7. **Arguments in Support.** The California Naturopathic Doctors Association writes, "The vast majority of naturopathic doctors practice primary care medicine. Unfortunately, current law creates obstacles for patients who have chosen to see an ND for their primary care needs. Specifically, these patients must be referred out for medication management or minor procedures, such as stitching a cut, despite the fact that their doctor is trained to do these things. Both of these limitations increase cost and delay care for patients. This delay in care can result in patient harm if acute conditions (e.g. strep throat) are not treated in a timely manner. In addition, current scope limitations are a barrier to the growth of the naturopathic profession in California, compounding the primary care provider shortage in this state.

"Increasing demands for primary care doctors and health care services are adding stress to an already overburdened health care system. It is therefore vital to improve patient access to licensed primary care doctors who are trained to independently perform all primary care needs."

8. **Arguments in Opposition.** The California Medical Association and the California Association of Family Physicians were in opposition to the prior version of this bill and stated the following: "The distinctive philosophy of naturopathic medicine and many of its methods of diagnosis and treatment are unscientific in concept, biologically improbable and clinically unproven. Moreover, regardless of its theory, the scope and quality of naturopathic education do not prepare its practitioners to make either an adequate diagnosis or provide appropriate treatment independent of

medical doctors. Naturopathic services are not covered by Medicare or most insurance policies for good reason: a lack of evidence of appropriate effectiveness. Only 17 states allow the practice of naturopathic medicine and California is the only large state among them.”

9. **Related Legislation.** SB 1446 (McLeod, Chapter 333, Statutes of 2012) allowed naturopathic doctors to independently prescribe and administer vitamins, minerals, amino acids, glutathione, botanicals and their extracts, homeopathic medicines, electrolytes, sugars, and diluents, as specified. It also required NDs to demonstrate compliance with specified requirements, including the successful completion of specified coursework by a provider approved by the Committee, in order to qualify for intravenous therapy administration, and clarifies the types of substances a ND may prescribe and administer.

SB 1246 (McLeod, Chaptered 523, Statutes of 2010) included NDs in the list of health care practitioners who could perform specified clinical laboratory tests, defined a naturopathic assistant for purposes of the Act, and specifies certain functions for naturopathic assistants.

AB X4 20 (Strickland, Chapter 18, Statutes of 2008) abolished the Bureau of Naturopathic Medicine and created the Naturopathic Medicine Committee within the Osteopathic MBC.

SB 907 (Burton, Chapter 485, Statutes of 2003) established the Act to be administered by the Bureau of Naturopathic Medicine within the Department of Consumer Affairs.

SUPPORT AND OPPOSITION:

Support:

California Naturopathic Doctor Association (Sponsor)
 AARP
 Akasha Center for Integrative Medicine
 American Association of Naturopathic Physicians
 Arizona Naturopathic Medical Association
 Bastyr University
 California Chiropractic Association (CCA)
 California Naturopathic Clinic
 California Naturopathic Medicine Committee
 Center for Health Santa Cruz
 Endocrinology Association of Naturopathic Physicians
 Integrative Medicine for the Underserved (IM4US)
 National College of Natural Medicine
 Naturopathic Academy of Primary Care Physicians
 Paracelsus Natural Family Health Center
 Pediatric Association of Naturopathic Physicians
 Santa Cruz Naturopathic Medical Center
 Southwest College of Naturopathic Medicine and Health Sciences

Stengler Center for Integrative Medicine
The Oncology Association of Naturopathic Physicians
Washington Association of Naturopathic Physicians
Women's View Medical Group, Inc.
1,155 Individuals

Opposition:

American Academy of Pediatrics
American Congress of Obstetricians and Gynecologists
California Academy of Family Physicians
California Chapter of the American College of Cardiology
California Chapter of the American College of Emergency Physicians
California Medical Association
California Orthopaedic Association
California Radiological Society
California Society of Anesthesiologists
California Society of Dermatology and Dermatologic Surgery
California Society of Plastic Surgeons
Kaiser Permanente
Osteopathic Physicians and Surgeons of California (OPSC)

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