

Attached is the ND Supervising Physician agreement that we have available as a sample document for our NDs. This sample document is for the convenience, information and use of NDs and may be duplicated. We recommend that the sample document be modified as consistent with the law and appropriate to the ND's practice, arrangement with the physician, and agreed upon protocols.

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General Agreement To Supervise A Naturopathic Doctor in California

Summary Statement For Physicians

In 2003, the state of California began regulating Naturopathic Doctors (NDs) in passing the Naturopathic Doctors Act (SB907). The Act can be found in the California Business and Professions Code in Division I, section 8.2 (or at www.naturopathic.ca.gov). The Act allows Naturopathic Doctors to, among other things, diagnose disease, order laboratory tests and diagnostic imaging, and order prescription drugs and non-prescription drugs in order to treat disease.

The Act does, however, place limitations on Naturopathic Doctors with regards to ordering drugs. When the California legislature was considering regulating Naturopathic Doctors, the legislature felt there was insufficient information available to determine what drugs Naturopathic Doctors should be able to prescribe. In order to facilitate passage of the Act, the Act was written to allow NDs to order all prescription drugs, except for Schedule 1 and 2 drugs, under the supervision of a California Physician. Only Schedule III drugs require a "patient specific protocol which is approved by the physician".

The exceptions to the above supervisory requirements are natural and synthetic hormones - which NDs are allowed to prescribe without supervision. Of note is testosterone. This drug, which is a hormone, may be prescribed by ND's without MD protocol/supervision. It also happens to be a Schedule III drug, which does require the ND to possess a DEA license to order. Thus, if the ND has a DEA license number, this particular drug/hormone may be ordered by the ND without MD supervision.

While establishing the supervisory requirement, the Act also established a Naturopathic Formulary Advisory Committee, comprised of NDs, MDs and Pharmacists, to further recommend scope and supervision requirements of an ND. This group ultimately developed a formulary of drugs that they felt NDs should be able to order without supervision. A copy of the recommended Naturopathic Formulary is available for background information. However, until the formulary is written into law, NDs must comply with the supervisory requirements of the Act.

The requirements for a supervising Physician are very similar to the supervisory requirements that Physicians have with Nurse Practitioners. The Act specifically references the supervisory procedures and protocols in the Nurse Practitioner laws as the procedures and protocols to follow for supervising NDs. Thus, if a Physician is familiar with the practice of supervising a Nurse Practitioner to order drugs, they are likely to be comfortable with the supervisory requirements of supervising a Naturopathic Doctor's drug orders.

The main two questions that commonly arise when a Physician is considering supervising a Naturopathic Doctor have to do with (1) malpractice insurance coverage and (2) how often the Naturopathic Doctor is likely to order prescription drugs.

Ensuring proper malpractice insurance for drug orders: two main options to consider.

1. You should be able to provide malpractice insurance under your current policy by adding the ND to the list of individuals you supervise. In most cases, your insurance carrier will not be familiar with NDs and may state that their policy does not

specifically cover NDs. However, most malpractice plans allow Physicians to cover a wide variety of healthcare professions.

This is usually covered under the supervisory section of your insurance plan under a heading called "vicarious others" (or a similar heading). Coverage may result in an increase in your malpractice insurance policy and can be reimbursed by the Naturopathic Doctor.

2. A Naturopathic Doctor's malpractice policy may include an optional "insurance rider" that covers the supervising

Physician. Determine if the amount of coverage is suitable to your needs.

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How often the Naturopathic Doctor is likely to prescribe.

When considering supervising a Naturopathic Doctor, you should try to understand how often the ND is likely to order drugs and what kind of substances they will order. NDs tend to provide drug orders on a very limited basis but you should have a

general understanding of the type of practice your ND has, the ND's training, how often s/he writes drug orders, and for what types of prescription substances. This should be discussed when reviewing this agreement.

As a point of reference, a December 2008 survey of 113 Naturopathic Physicians in Oregon, who are allowed to independently prescribe a wide range of controlled substances, found that the vast majority wrote less than 10 prescriptions a month. Specifically:

- Hormones for women accounted for the largest drug category of substances prescribed. Since California NDs can already independently prescribe hormones, they do not require MD supervision.
- Pain medication was the second largest category of substances prescribed with 38% writing less than 10 prescriptions a month and only 5% writing more than 10 prescriptions per month for pain meds.
- Approximately 86% of ND's prescribe various drugs other than hormones and pain medications with only 18% writing more than 10 prescriptions a month.

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Sample Supervision Agreement Between Naturopathic Doctor And Supervising Physician

[Optional language is italicized.]

, M.D./D.O. ("Supervising Physician") [the

THIS Supervision Agreement ("Agreement") is entered into between

physicians whose signatures appear below, each of which shall be referred to herein as "Supervising Physician"], and N.D. ("ND"), in order to fulfill the purposes set , 20 .

N.D. ("ND"), in order to fulfill the purposes se forth below on the effective date of

1. <u>Purpose</u>. The purpose of this Agreement is to comply with the requirements of Business & Profession Code Sections 3640.5 and 2836.1, hereinafter referred to as the "ND Furnishing Or Ordering Drug Statutes." This Agreement allows ND to furnish or order drugs in accordance with standardized procedures or protocols developed collaboratively by ND and Supervising Physician. Drugs include any substance that requires a prescription from a Physician in the state of California.

2. **Qualifications.** ND is licensed by the California Bureau of Naturopathic Medicine. Supervising Physician is licensed by the Medical Board of California or the Osteopathic Medical Board of California and is qualified to act as a supervising physician. ND and Supervising Physician are familiar with the requirements governing the ordering or furnishing of drugs by NDs, and the supervision of NDs by supervising physicians.

3. Drug Orders.

(a) ND may administer or provide medication to a patient, or issue a drug order, orally or in writing in a patient's chart or drug order form, subject to the conditions and limitations as set forth in Sections 2836.1 and 3640.5 of the Business and Professions Code, this Agreement, any applicable protocols as described in subsection (b) below, or the specific instructions of Supervising Physician. Such medications may include Controlled Substances in schedules III through V. Schedule I and Schedule II drugs are outside of this Agreement because they are not within the scope of practice of a Naturopathic Doctor in California. ND may sign for the request and receipt of samples of drugs specified in the protocols described in subsection (b) below.

(b) Drug orders shall either be based on protocols established or adopted by Supervising Physician, or shall be approved by Supervising Physician for the specific patient prior to being issued or carried out. Notwithstanding the foregoing, all orders for Schedule III drugs shall be approved by Supervising Physician for the specific patient prior to being issued or carried out. A copy of a written order or approval will be kept in the patient's medical record and a verbal order or approval shall be documented in the patient's medical record and include the time and date of the order or approval.

- (c) "Order," or "drug order," means an order for medication which is dispensed to or for a patient as an ultimate user, issued by the Naturopathic Doctor as an individual practitioner, within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations, and, orders.
- (d) The ND agrees that if s/he needs to consult with the supervising Physician for any reason, the ND
 will not provide a patient with the drug order until the consultation between the supervising Physician
 and ND has taken place.
- (e) The ND shall enter each and every drug order issued by the ND under this Agreement into the
 medical records of the patient. If, after consultation between the two parties, the Supervising Physician
 orders a different drug than the ND recommends, this shall also be noted in the patient's medical record.

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(f) The ND shall transmit each drug order in compliance with all applicable medical laws in California regarding the transmission of drug

(g) The ND agrees to maintain a log of all drugs ordered under this agreement and to maintain a copy of

this agreement at his/her practice for inspection by a pharmacist or the Supervising Physician.

(h) It is understood that any order written, signed or transmitted, or drug dispensed by a ND under the supervision of a Supervising Physician shall be treated in the same manner as a prescription of the Supervising Physician and that the signature of the ND shall be deemed to be that of a prescriber for purposes of the California Health and Safety Code.

4. Supervising Physician Responsibilities.

- (a) Supervising Physician shall remain electronically available at all times while ND is performing medical services, unless another approved supervising physician who has signed an Agreement to Supervise for ND is so available. Supervising Physician does not need to be present at the facility where the supervised ND will exercise ordering privileges.
- (b) If the Supervising Physician is unavailable for a period of time, s/he may name an alternate Supervising Physician who will be covered under this Agreement and may provide medical supervision for ND.

5. Protocols.

This Supervision Agreement does not constitute the protocols required by 2836.1 and 3640.5 of the Business and Professions Code. Such protocols are on file at the practice site and may incorporate by reference appropriate medical texts.

6. No Third Party Beneficiaries.

This Agreement shall not be construed as creating rights in or obligations to any third party. It is the intent of the parties solely to fulfill the requirements of Business & Profession Code Sections 3640.5 and 2836.1, hereinafter referred to as the "ND Furnishing Or Ordering Drug Statutes" and for the mechanisms to be used by Supervising Physician in supervising ND.

7. Te

Dated:

erm Of Agreement.			
above. Either party meaning party notice of such e	hay elect to cancel this ag election to cancel, in writin ate of cancellation. Cand	years from the dat reement on an earlier date ig, received by the other pa cellation of the agreement i	certain, by providing the other arty not less than days
Dr	MD /	Dr	ND
DO Licensed California	a Supervising	Licensed Naturop	athic Doctor, License
Physician		#	

Dated:

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ADDITIONAL SUPERVISING PHYSICIANS	5.
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Dr	MD/				
DO Licensed California Supervising					
Physician					
Dated:					
Dr	MD /				
DO Licensed California Supervising					
Physician					
Dated:					

Sample

Protocol: Drugs & Devices

Definition: This protocol covers the management of drugs and devices for patients presenting to Dr. _____,ND. The naturopathic doctor (ND) may initiate, alter, discontinue, and renew medication included on, but not limited to the attached Formulary. All schedule I & II drugs are excluded.

Subjective Data:

Subjective information will include, but is not limited to:

- 1. Relevant health history to warrant the use of the drug or device
- 2. No allergic history to the specific drug or device

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No personal and/or family history which is an absolute contraindication to use the drug or device

Objective Data:

- 1. Physical examination appropriate to warrant the use of drug or device
- 2. Laboratory tests or procedures to indicate/contraindicate use of drug or device if necessary

Assessment:

Subjective and objective information consistent for the use of the drug or device and there should be no absolute contraindications for the use of drug or device.

Plan:

- 1. Plan of care to monitor effectiveness of any medications or device.
- Patient education: Provide the client with information and counseling in regard to the drug or device. Caution client on pertinent side effects or complications with chosen drug or device.

Consultations and/or referrals:

Non-responsiveness to appropriate therapy and/or unusual or unexpected side effects and as indicated in general policy statement.

MD Supervision & Review:

- 1. All prescribed drugs under this agreement will be faxed to Supervising Physician once per month to [fax number]. If no prescriptions dispensed, electronic report will be faxed by end of each month and read "Nothing to Report." Prescribing document will include patient's name, diagnosis, specific medication, dose prescribed, and date. If renewal (refill) of previously prescribed medication, document will include patient's name, medication and dose, and number of refills.
- 2. All orders for Schedule III drugs shall be approved by Supervising Physician for the specific patient *prior* to being issued or carried out.

Formulary

Antimicrobial agents (such as, but not limited to: anti-fungals, anti-parasitics, anti-bacterials)

Anti-viral agents (such as, but not limited to: acyclovir, famciclovir)

Cardiovascular agents (such as, but not limited to: ARBs, BB, CCBs, statins)

Dermatologic agents (such as, but not limited to: topical anti-bacterials, topical anti-fungals)

Endocrine agents (such as, but not limited to: tapazole, methimazole, bromocryptine)

Gastrointestinal agents (such as, but not limited to: bismuth subsalicylate, anti-microbials, H2 blockers, PPIs)

Immunologics (such as, but not limited to: antihistamines)

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Neurologic/Psychiatric agents (such as, but not limited to: analgesics, anti-depressants, anti-anxiety)

Pulmonary agents (such as, but not limited to: albuterol, Advair, Symbicort, anti-tussives, decongestants, expectorants)

Other pharmaceutical agents as deemed necessary and approved by Supervising Physician (Excludes Schedule I & II)