

MINOR OFFICE PROCEDURES FINDINGS & RECOMMENDATIONS

CONSULTANT FINDINGS

California's Need for Access to Competent Medical Care

The inclusion of a provision for Minor Office Procedures in the Act was based in part on serving underserved citizens of California, particularly those in urban centers and rural areas. Given the current cost of health care, an ever-growing uninsured population, increased use of the Emergency Room for non-urgent care, and the decreased number of physicians serving the citizens of California, allowing NDs to perform minor office procedures, as trained, better serves Californians while still protecting the public from dangerous practices.

Minor Office Procedures Taught in the Naturopathic Colleges

Each of the approved schools requires completion of minor office surgery courses, medical procedure courses, or courses in emergency medicine. A listing of the required hours for graduation at each school is given above under the section entitled Approved Schools. Samples of syllabi from two of the courses are given in the Appendix.

Minor Office Procedures Laws from other States

The states that currently allow minor office procedures or minor office surgery to be performed by NDs are Arizona, Idaho, Kansas, Maine, Montana, New Hampshire, Oregon, Utah, and Washington. The procedures that are allowed in all of those states appear to be the use of electrical or other methods for the surgical repair and care of superficial lacerations and abrasions, removal of benign superficial lesions, the removal of foreign bodies and masses located in the superficial structures, and the use of antiseptics and local anesthetics. The specific laws from these states appear in the Appendix.

Minor Office Procedures Currently Practiced by Licensed NDs in the Field

An informal survey of Naturopathic Doctors in those states which do allow minor surgery or minor office procedures was performed by the consultants in preparation for this report. The survey revealed the following procedures in current use by NDs in their offices:

- Local anesthetics
- Repair of superficial lacerations

- Drain and pack abscesses in the dermis and subcutaneous tissue
- Drain bursas
- Remove superficial lesions, moles, lipomas, warts, nevi, ganglions, fibromas, cysts, foreign bodies, excision and biopsy
- External hemorrhoids (including infrared and laser)
- Kesy (electrogalvanic coagulation) to treat internal hemorrhoids)
- Stitch surgical and non-surgical wounds, debride wounds
- Trephination of eardrums,
- Trigger point injections
- All types of injection therapy including trigger point injection, NT, MFTPi, IV, mesotherapy, prolotherapy, sclerotherapy, "dry needling", etc
- Light based therapies (intense pulsed light, laser, Levulon, broad band) for skin procedures
- Dermatological peels, facial fillers
- Electrocauterization, hyfercation, cryosurgery
- Escharotic therapy – warts, moles, cervical lesions
- Punch biopsies
- Scar therapy
- Removal of impacted cerumen
- Wound & decubitis ulcer care

In researching for this report, the Bureau was unable to identify any cases of malpractice regarding minor office procedures by an ND in any of the states where these procedures are allowed.

Laboratory Testing

Section 3640 of the Business and Professions Code authorizes an ND to “order and perform” physical and laboratory examinations for diagnostic purposes, including, but not limited to, phlebotomy, clinical laboratory tests, speculum examinations, orificial examinations, and physiological function tests.

The federal Clinical Laboratory Improvement Amendments (CLIA) law (42 U.S.C. Sec. 263a; P.L.100-578) requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain requirements. If a facility (e.g. ND’s office) performs tests for these purposes, it is considered under the law, to be a laboratory. CLIA laws apply even if only one or a few basic tests are performed, and even if there is no charge for the testing. CLIA standards apply nationwide and require that a lab director is to be designated for testing that is beyond the “waived” category. Waived tests include the simplest tests, such as a home pregnancy test that can be purchased over the counter.

Federal regulations define waived tests as simple laboratory examinations and procedures that are cleared by the Food and Drug Administration (FDA) for home use; employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or pose no reasonable risk of harm to the patient if the test is performed incorrectly (42 C.F.R. 493).

The specified tests that are listed in the regulation are:

1. Dipstick or Tablet reagent urinalysis (non-automated) for the following:
 - Bilirubin
 - Glucose
 - Hemoglobin
 - Ketone
 - Leukocytes
 - Nitrite
 - pH
 - Protein
 - Specific gravity
 - Urobilinogen
2. Fecal occult blood
3. Ovulation tests - visual color comparison tests for luteinizing hormone
4. Urine pregnancy tests - visual color comparison tests
5. Erythrocyte sedimentation rate-non-automated
6. Hemoglobin-copper sulfate - non-automated
7. Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use
8. Spun microhematocrit
9. (added 1/19/93) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout

However, state law (Section 1206.5) requires that any facility where clinical lab tests are performed, even those classified as “waived” must be performed under the overall operation and administration of a lab director. A lab director is defined as either a licensed medical doctor, or a person licensed as a lab director under the Business and Professions Code. Therefore, unless an ND is licensed as a lab director, all clinical tests must be performed under the operation and administration of an MD, or other licensed lab director. It should also be noted that NDs (and other healthcare professionals) practicing in other states do not have any similar type of restriction and are able to perform these tests as authorized within the federal law.

It is clear that it was the intent of the Legislature when it enacted Section 3640 to authorize NDs to be able to perform the tests as specified in the Act. The restriction in state law severely limits the ability of the NDs to practice their profession and to provide the safest level of care for their patients.

CONSULTANT RECOMMENDATIONS

After a review of the training, education, and practice of NDs, the consultants reached consensus regarding procedures which, when performed by competent, properly trained NDs, present low risk to patients. The procedures listed below are recommended to be able to be performed by NDs without MD supervision:

- Prescribe and administer local anesthetic solutions, their adjuncts and diluents (topical and injected)
- Removal of clinically benign skin lesions
- Repair of skin lacerations (including suturing)
- Removal of superficial tissue foreign bodies or lesions
- Incision and drainage of abscess / trephination of subungual hematoma

The Act already allows for the "removal of foreign bodies located in the superficial tissues" (Section 3640(c)(6)). The Act would need to be amended to allow NDs to perform the other four procedures recommended by the consultants.

Laboratory Testing

It is recommended that statutory changes be made in order to allow NDs to be able to perform the clinical laboratory tests authorized by Section 3640 of the Act.