



Effective March 22, 2006

Protecting, maintaining and improving the health of all Minnesotans

March 17, 2006

Ms. Kristi Hughes Hawkes
[REDACTED]

RE: Determination affecting your naturopathic practice.

Dear Ms. Hughes Hawkes:

Based on my review of the attached document outlining the facts and law in this matter, I have determined that you must immediately cease using any TENS units and other medical devices restricted by federal law as required by Minnesota Statutes, § 146A.01, subd. 4(b) and 21 C.F.R. § 801.109.

You have the right to challenge this decision in a contested-case hearing as provided under Minnesota Statutes, Chapter 14. Requests for hearing should be made in writing and include specific grounds for challenging the Department's decision. If you wish to request a hearing, please send, deliver, or fax a written hearing request within 30 days of your receipt of this letter to:

Susan Winkelmann, Investigations and Enforcement Manager
Minnesota Department of Health
85 East Seventh Place, Suite 300
P.O. Box 64882
St. Paul, MN 55164-0882
Fax (651) 201-3839

If you have any questions about this matter, contact Ms. Susan Winkelmann, at (651) 201-3722.

Sincerely,

A handwritten signature in cursive script that reads "D. J. Giese".

David J. Giese, Director
Division of Compliance Monitoring

cc: Susan Winkelmann, Investigations and Enforcement Manager
Tom Hiendlmayr, Health Occupations Program Director

**HEALTH OCCUPATIONS PROGRAM
MINNESOTA DEPARTMENT OF HEALTH**

**A Determination In the Matter of Kristi Hughes Hawkes
Unlicensed Complementary and Alternative Health Care Practitioner**

AUTHORITY

1. Minnesota Statutes, § 146A.09, subd. 1, provides that the Office of Unlicensed Complementary and Alternative Health Care Practice (hereinafter "OCAP") within the Minnesota Department of Health (hereinafter "Department") has the authority to revoke, suspend, censure, reprimand, impose limitations or conditions, and impose a civil penalty not exceeding \$10,000 for each separate violation, the amount of the civil penalty to be fixed so as to deprive the practitioner of any economic advantage gained by reason of the violation or to reimburse the office for all costs of the investigation and proceeding when there is a violation of law as defined in Minnesota Statutes, § 146.08, subd. 1.
2. Pursuant to Minnesota Statutes, § 146A.01, subd. 4(a), complementary and alternative health care practices include the broad domain of complementary and alternative healing methods and treatments, including but not limited to: (20) naturopathy.
3. Minnesota Statutes, § 146A.01, subd. 6(a)(1)(i) defines a complementary and alternative health care practitioner as being one who is not licensed or registered by a health-related licensing board or the commissioner of health
4. Minnesota Statutes, § 146A.01, subd. 4(b) prohibits complementary and alternative health care practitioner from engaging in surgery, x-ray radiation, administering or dispensing legend drugs and controlled substances, practices that invade the human body by puncture of the skin, setting fractures, and the use of medical devices as defined in § 147A.01.
5. Minnesota Statutes, § 147A.01, subd. 16 defines medical devices as durable medical equipment and assistive or rehabilitative appliances, objects, or products that are required to implement the overall plan of care for the patient and that are restricted by federal law to use upon prescription by a licensed practitioner.
6. 21 U.S.C. § 360c(a)(1) designates three classes of medical devices regulated by the Federal Food and Drug Administration.
7. 21 C.F.R. § 882.5890 classifies transcutaneous nerve stimulators (also called "TENS") as Class II medical devices. 21 C.F.R. § 860.3 (c)(2) states "A device is in class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is sufficient information to establish special controls, including the promulgation of performance standards, postmarket surveillance, patient registries,

development and dissemination of guidance documents, recommendations, and other appropriate actions as the [FDA] deems necessary to provide such assurance.”

8. 21 C.F.R. § 801.109 mandates that some medical devices can only be used under the supervision of a licensed practitioner because of the potentiality of harmful effect. These devices must either be in the possession of a person who regularly and lawfully engages in the manufacturer, transportation, storage of such devices, or in the possession of licensed practitioners, and can only be sold to or on the prescription of licensed practitioners. This provision in federal law requires a particular label to be used on the device that states the device is restricted to be used by only licensed practitioners.

FINDINGS OF FACT

1. Practitioner has been and is subject to the jurisdiction of the Department because Practitioner engages in unlicensed complementary and alternative health care practice as defined in Minnesota Statutes, § 146A.01.
2. Practitioner is not now, nor has she ever been licensed or registered by the Minnesota health-related licensing boards or the commissioner of health in Minnesota.
3. Practitioner has been a practicing naturopath in Minnesota since 1997 and founded the Center of Natural Healing Arts, Inc., which has offices in Alexandria and Moorhead, Minnesota. Practitioner is a graduate of the National College of Naturopathic Medicine in Oregon.
4. The Department issued a Stipulation and Consent Order against Practitioner effective June 29, 2005. As one of the terms of the Stipulation and Consent Order, Practitioner was required to disclose each TENS unit or frequency specific microcurrent machine Practitioner uses in her practice. Practitioner was required to include a copy of the label from each machine to show whether each was restricted by the Federal Food and Drug Administration (FDA) to be used only by licensed practitioners.
5. Practitioner submitted a list of equipment she uses and there are eleven Transcutaneous Electrical Nerve Stimulators (TENS) units, five of which are home care units for use by Practitioner’s clients at their homes. The FDA’s 510(k) Premarket Notification Registration listing for these devices determines each is a Class II medical device manufactured by Precision Microcurrent, Inc., Vancouver, Washington.
6. Practitioner’s medical device labels show the following:
 - a. Two TENS units, numbers 352 and 521 manufactured by Precision Microcurrent. Labels each state “Federal law restricts this device to sale by or on the order of a qualified physician licensed by the law of the state in which he practices to use or order the use of this device.”

b. Three Model E-275 devices identified with the following descriptor-label, "Computer Aided Galvanic Minimal Electrical Cosmetology Device", numbers 101189, 101199, 100536. Labels each state, "This is a cosmetic device only, to be used only by a licensed cosmetologist or practitioner, under applicable laws. To be used only on the superficial tissues of the skin. Not to be used through the brain area, on pregnant women, on persons wearing pacemakers or near pacemakers."

c. Two Auto Care 275 devices, numbers AC 1017 and AC 1088. Labels each state, "Federal Law restricts this device to sale by or on the order of a practitioner licensed by the law of the state in which he/she resides. This device is intended exclusively for use as Transcutaneous Electrical Nerve Stimulator in the treatment of pain. To be used only on the superficial tissues of the skin. Not to be used through the brain areas, on pregnant women, persons wearing pacemakers, or near pacemakers."

d. The Home Care Units did not have labeling on them.

7. In an e-mail dated July 10, 2005, Practitioner explained that while she was attending the National College of Naturopathic Medicine in 1996 and 1997, she was employed at the Portland Fibromyalgia and Myofascial Pain Clinic working with a licensed chiropractor, Dr. Carolyn McMakin. Practitioner explained that she used TENS units in her work in Portland. When Practitioner moved to Minnesota in 1997, Practitioner continued her use of TENS units in her practice. Practitioner believes that since she is "licensable" as a Naturopath in states that license naturopaths, she can use TENS units in Minnesota. Practitioner purchased the TENS units directly from the manufacturer.

8. On the Establishment Registration Database of the FDA, the Official Correspondent or contact person in Precision Microcurrent, Inc., is Dr. Carolyn McMakin.

9. For the last four years, Practitioner has been teaching the use of TENS units for pain management to various health care professionals around the nation. Practitioner conducts these courses with Dr. Carolyn McMakin.

10. Department staff consulted with the Midwest regional office of the FDA and FDA staff evaluated the documents Practitioner provided about her medical devices. The FDA concluded that each of the medical devices were prescription devices therefore only allowing persons licensed by Minnesota to use the devices or order their use.

CONCLUSION AND DETERMINATION

Practitioner violated Minnesota Statutes, sections 146A.08, subs. 4(b). Practitioner must immediately cease using any of the TENS' units described in this document as well as any other medical device restricted by federal law.