Effective 8-10-07

MINNESOTA MDH DEPARTMENT OF HEALTH

Protecting, maintaining and improving the health of all Minnesotans

August 8, 2007

Ms. Shirley Vedder
[redacted]

RE: MDH File Number: 200655

Dear Ms. Vedder:

Based on the facts and law in this matter as described in the enclosed Staff Determination, the Minnesota Department of Health (MDH) has determined that you violated Minnesota Statutes, section 146A.01, subdivision 4(b) prohibiting the use of certain medical devices, section 146A.08, subdivision 1(e) prohibiting false or misleading advertising, section 146A.08, subdivision 1(f) prohibiting conduct likely to deceive, defraud or harm the public, and section 146A.06, subdivision 1 requiring practitioners to fully cooperate with investigations conducted by the MDH. Therefore, MDH is revoking your right to practice unlicensed complementary and alternative health care in Minnesota.

This decision will be made final and effective 30 days from the date it is received by you. During that 30-day period, you have the right to challenge this decision in a contested-case hearing, as provided under Minnesota Statutes, Chapter 14. Requests for a 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 a written hearing request, within 30 days of your receipt of this letter, to:

Susan Winkelmann, Investigations and Enforcement Manager
Minnesota Department of Health
PO Box 64882
Saint Paul, MN 55164-0882

You may also deliver your request to 85 East Seventh Place, Suite 220, Saint Paul, MN; or fax it to Ms. Winkelmann at (651) 201-3839. If you have any questions about this matter, please contact Susan Winkelmann at (651) 201-3722.

Sincerely,

Darcy Miner

Darcy Miner, Director
Compliance Monitoring Division

Enclosure

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

HEALTH OCCUPATIONS PROGRAM
MINNESOTA DEPARTMENT OF HEALTH
A Determination In the Matter of
Shirley Vedder
Unlicensed Complementary and Alternative Health Care Practitioner

AUTHORITY

1. Minnesota Statutes, section 146A.09, subdivision 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 to exceed $10,000 for each separate violation, with 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, section 146.08, subdivision 1.

2. Pursuant to Minnesota Statutes, section 146A.01, subdivision 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: (8) energetic healing; (10) folk practices; (11) healing practices utilizing the physical forces of heat, cold, water, touch and light; and (21) noninvasive instrumentalities.

3. Minnesota Statutes, section 146A.01, subdivision 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, section 146A.01, subdivision 4(b) prohibits complementary and alternative health care practitioners from the use of medical devices as defined in Minnesota Statutes, section 147A.01.

5. Minnesota Statutes, section 147A.01, subdivision 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. Title 21, U.S.C., section 360c(a)(1), designates three classes of medical devices regulated by the Federal Food and Drug Administration.

7. According to information from the Federal Food and Drug Administration's Center for Devices and Radiological Health (CDRH), ear candling/coning devices are considered to

be medical devices and because there is no Premarket Approval or Premarket Notification of these products, they cannot be legally marketed in the United States. CDRH considers the products to be dangerous when used according to the labeling since the use of a lit candle in the proximity of a person's face carries a high risk of causing potentially severe skin and hair burns and middle ear damage.

8. Minnesota Statutes, section 146A.06, subdivision 1 requires complementary and alternative health care practitioners to cooperate fully with OCAP in investigations.

9. Minnesota Statutes, section 146A.08, subdivision 1 (e) prohibits advertising that is false, fraudulent, deceptive, or misleading.

10. Minnesota Statutes, section 146A.08, subdivision 1 (f) prohibits conduct likely to deceive, defraud or harm the public, or any other practice that may create danger to any client's life, health, or safety, in any of which cases, proof of actual injury need not be established.

FINDINGS OF FACT

1. Practitioner is, and has been, subject to the jurisdiction of the Department because Practitioner engages in unlicensed complementary and alternative health care practice as defined in Minnesota Statutes, section 146A.01.

2. Practitioner is not licensed or registered by either any of the health-related licensing boards or the commissioner of health in the State of Minnesota, including the Minnesota Board of Nursing.

3. Practitioner advertised in the *Edge Life* newspaper in the Twin Cities area of Minnesota as an ear candler from November 2005 to June 2007. Practitioner's 2005-2006 advertisements read as follows: "Ear Coning/Candling is an ancient healing process to painlessly relieve pressure and congestion in the sinuses and ears. Removes excess ear wax to improve hearing. Chronic ear infections & fluid in the ears—I do children as young as 3 years old. Relieve congestion in the sinuses from allergies or infection. Clear meridians for balance—great for yoga. Frequent fliers with plugged ears. Tinnitus-ringing in the ears. Meniere's disease—vertigo, dizziness. Shirley Vedder (Nurse)".

4. Practitioner's website on April 26, 2006, Practitioner stated, "I was a volunteer in my hometown hospital and continued on to become an RN. I have had over 20 years of service in that field. Since 1997, I have been doing ear Coning/Candling and also using energy based healing."

5. In a letter dated August 4, 2006, Department staff notified Practitioner about her engaging in ear candling and her advertisements and requested a written response by

September 7, 2006. In a voicemail left on September 5, 2006, Practitioner asked for an extension for reply because she had just been released from the hospital and would be returning on September 6, 2006, for surgery. Department staff gave Practitioner an extension to October 5, 2006.

6. In the September 2006 *Edge Life* newspaper, Practitioner changed her advertisement by shortening the information to the following: "EAR CONING/CANDLING Ancient healing process to painlessly relieve pressure/congestion in the sinuses and ears. Shirley Vedder (nurse)".

7. When Practitioner did not respond by October 5, 2006, Department staff wrote Practitioner on October 16, 2006, requesting a response by October 26, 2006. In a voicemail received on October 26, 2006, Practitioner left a message stating that she had been very ill and would submit her written response on that day.

8. On October 27, 2006, the Department received Practitioner's short response in which she did not answer five of the seven questions asked. Practitioner did state that she had done ear coning on hundreds of people and they loved the experience. Practitioner said that she sees about 200 clients per year and charges $85 for the one and a half hour process. Practitioner assesses her clients by asking questions about their ears and sinuses and if she cannot help them, she refers them to the clients' physicians or an ENT. Practitioner buys the ear candling devices at health food stores and co-ops. Practitioner tells her clients that she was a nurse for over 20 years.

9. In a letter dated December 26, 2006, the Department wrote Practitioner a follow-up letter to obtain answers to the questions Practitioner did not answer in her October 27, 2006, letter. The Department requested a response by January 26, 2007. The Department sent two identical letters to Practitioner; one by certified mail and one by regular mail. The Postal Service returned the certified mail piece to the Department on January 12, 2007, after Practitioner refused to claim the letter. The letter sent by regular mail was not returned to the Department. Practitioner did not respond to the Department's letter.

10. On the *Edge Life* website on January 31, 2007, Practitioner's advertisement was the same as the one described in paragraph three above.

11. On March 26, 2007, Department staff verified Practitioner's address by going to her address. Department staff noted that Practitioner's name was next to the security buzzer and next to that was a sign advertising Practitioner's ear candling business.

12. On March 29, 2007, Practitioner spoke to Department staff and said that she did not receive the Department's December 2006 letter. Department staff sent a confirmation letter about this telephone conversation and enclosed a copy of the December 2006 letter

and again requested a response. The Department sent two letters; one by certified mail and one by regular mail. Practitioner refused to claim the letter sent by certified mail. The letter sent by regular mail was not returned to the Department.

14. When no response was received by April 24, 2007, Department staff called Practitioner and left a voicemail message for Practitioner. In a voicemail received on April 30, 2007, at 7:23 PM from Practitioner, she stated that she did not even know where the Department's letter was and the Department's questions about medical device registration numbers were not relevant since what she was doing was not a medical treatment. Practitioner stated that her activities were a holistic treatment and that the OCAP law allowed her to engage in ear candling.

15. In a letter dated May 18, 2007, Department staff responded to Practitioner's voice-mail left on April 30, 2007 and again explained the OCAP and the statutes regulating her practice. A copy of the December 2006 letter was enclosed with a request to provide a response by June 18, 2007, or face suspension or revocation of her practice.

16. Practitioner did not respond to the May 18, 2007, letter from the Department.

CONCLUSION AND DETERMINATION

1. Practitioner violated Minnesota Statutes, sections 146A.01, subdivision 4(b).

2. Practitioner violated Minnesota Statutes, section 146A.06, subdivision 1, requiring full cooperation from Practitioners under investigation by OCAP.

3. Practitioner violated Minnesota Statutes, sections 146A.08, subdivision 1 (e) and (f).

4. Practitioner's right to practice unlicensed complementary and alternative health care in Minnesota is revoked.

5. Regarding Practitioner's ear candling/ear coning practice, Practitioner must immediately cease using any of the ear coning or ear candling devices described in this document as well as any other medical device restricted by federal law.

6. Regarding Practitioner's ear candling/ear coning practice, Practitioner must immediately cease any and all advertising for ear coning and/or ear candling or any related practice which utilizes illegal medical devices.

7. Regarding Practitioner's representation of her credentials, Practitioner must immediately cease any and all advertising stating she is a nurse in Minnesota.