

**Office of Unlicensed Complementary and Alternative Health Care Practice
Minnesota Department of Health
Biennial Report
July 1, 2002 to June 30, 2004**

I. General Information

A. Office Of Unlicensed Complementary and Alternative Health Care Practice Mission and Major Functions:

Mission:

To protect consumers who receive complementary and/or alternative health care services from practitioners who fall outside of state licensing authorities, including, but not limited to, persons who provide: massage therapy, body work, homeopathy, naturopathy, herbology, healing practices utilizing food, food supplements and nutrients, healing touch, culturally traditional healing practices, and traditional Oriental practices. The Office of Unlicensed Complementary and Alternative Health Care Practice (hereinafter "OCAP") was created within the Minnesota Department of Health (hereinafter "Department") to receive and investigate complaints against unlicensed complementary and alternative health care practitioners, to take enforcement action for violations of prohibited conduct, monitor practitioner conduct after discipline, and act as an information clearinghouse by providing the public with information about regulation of unlicensed complementary and alternative health care practitioners in the state of Minnesota.

Major Functions:

Investigating complaints

- Accepting complaints and reports from the public, health care service providers, and other health care regulators regarding the conduct of unlicensed complementary and alternative health care practitioners.
- Determining whether a complaint or inquiry is jurisdictional and, if so, obtaining sufficient evidence to determine if a violation of Minnesota Statutes, Chapter 146A occurred.
- Engaging in fact-finding by interviewing complainants, witnesses, and the practitioners, and obtaining relevant documentation about the allegation(s) including a completed complaint form from the complainant.
- Coordinating investigations involving matters within the jurisdiction of more than one regulatory agency by making appropriate referrals to other state boards, agencies, departments responsible for licensing health related occupations, facilities and programs, and law enforcement personnel in this and other states.

- Informing complainants of action taken to resolve their complaints as allowed by the provisions of the Minnesota Government Data Practices Act.

Taking and enforcing disciplinary actions against all unlicensed complementary and alternative health care practitioners for violations of prohibited conduct

- Evaluating the case against a practitioner while balancing the constitutional due process rights of the practitioner against the Department's obligation to protect the public from harm in a cost effective way.
- Holding investigative conferences with practitioners to clarify information received during an investigation, identify the practitioner's role and responsibility in a matter under investigation, and allow the practitioner an opportunity to make a meaningful response.
- Obtaining voluntary and negotiated agreements with practitioners for discipline whenever possible.
- Protecting the identity of clients when sexual misconduct or other serious violations occurred.
- Subsequent to disciplinary action, setting up a system to continue monitoring practitioner's conduct to ensure it complies with the disciplinary Order.
- Taking further enforcement actions if there is evidence to conclude that practitioner violated terms of the Order of the Department.

Acting as informational clearinghouse on complementary and alternative health care services provided by unlicensed practitioners through dissemination of information to the public about avenues for relief, consumer rights, sexual exploitation by practitioners, and to practitioners about their legal responsibilities

- Being available by telephone or in writing to answer questions about regulations pertaining to unlicensed complementary and/or alternative health care service providers in Minnesota and consumer rights.
- Being available on-line via the website which provides information about regulation of unlicensed complementary and alternative health care practitioners in the state of Minnesota, consumer rights, how to file complaints against practitioners, and the requirements of the Client Bill of Rights.
- Preparing and distributing brochures and other printed materials to both

consumers and practitioners to describe consumer rights and options, to educate the public and practitioners about the OCAP and to inform practitioners about their legal responsibilities.

- Collecting and recording data about both investigations and enforcement actions for distribution to the public and legislative authorities about OCAP's activities.

B. Major Activities during the Biennium

- On September 27, 2002, the OCAP issued a press release about the regulation and how to file complaints and obtain information from the Department.
- On November 15, 2002, the OCAP was featured in an article in the *Business Journal* about complementary practices and the laws regulating them in Minnesota.
- In April of 2003, the OCAP contracted with a licensed physician to work as a medical consultant to OCAP. The physician's role is to assist OCAP on cases involving alleged illegal diagnoses of medical conditions and other medically related topics.
- In June 2003, KSTP, a local TV station, interviewed department staff as a follow up to one of its stories about complementary practitioners. The show was aired in August 2003.
- On March 31, 2004 OCAP hired a full-time Health Care Program Investigator to fill a staff vacancy left on December 26, 2002 to handle investigations, enforcement actions, and public information activities for the OCAP.
- During the biennium the OCAP received over two hundred (200) inquiries from the public and/or practitioners requesting information about unlicensed complementary and alternative health care practice. The OCAP mailed out approximately eight hundred fifty (850) brochures/information packets.

C. Emerging Issues Regarding Regulation of Unlicensed Complementary and Alternative Health Care Practitioners and Practices

- Continuing acceptance of complementary and alternative health care by Minnesotans demonstrates the need for regulatory oversight.
- A staff vacancy from December 26, 2002 to March 31, 2004 affected OCAP's activities. When the investigator position was left vacant in

December 2002, the vacancy remained until March 2004 because of general funded salary constraints within the Department. Instead, the Section reassigned existing staff and there were fluctuating staff levels throughout the biennium so that a thirty-case backlog of investigations was created during this time.

- There are numerous types of practices within OCAP. Of all the practice types, massage therapists/bodyworkers are the largest identifiable occupational group. Massage therapists/bodyworkers also receive the most complaints within OCAP. Of the complaints against massage therapists/bodyworkers, eighty-three percent (83%) of these allege sexual misconduct. This high percentage suggests a considerable problem with boundaries and sexual misconduct in the massage therapy/bodyworker group.
- OCAP has identified a new group of practitioners who claim to analyze blood cells and improve health by drawing blood from clients, viewing and evaluating blood on a computer screen with the client and then recommending dietary supplements. Drawing blood from clients is a violation of OCAP law, and there is also the potential for very serious public health issues if clients are substituting this care for other health care, ceasing taking prescribed medications or continuing to take prescribed medications along with dietary supplements which could negatively interact with medications.
- There are frequent points of contact between the OCAP and federal regulatory agencies that require delineation of authority and jurisdiction:

[1] Regarding OCAP's investigations of cell analyzers, the Federal Clinical Laboratory Improvement Act (CLIA) is a federal law requiring laboratories that test human specimens to meet certain laboratory standards and qualifications. The Act is administered by the Federal Department of Health and Human Services. CLIA issues arise in investigations where practitioners are drawing and testing blood and contending that their practice is exempted by CLIA. OCAP has contacted federal authorities and referred relevant portions of cases to them for investigation.

[2] Many OCAP practitioners also sell dietary supplements. The Federal Food and Drug Administration (FDA) in the Department of Health and Human Services regulates dietary supplement manufacturers through product labeling requirements. There is no federal or state regulation of dietary supplement ingredients, mixtures or the sellers themselves. OCAP does not have jurisdiction over persons only selling and distributing dietary supplements due to the federal law protecting that practice; however OCAP does have jurisdiction over complementary or alternative health care practitioners who also sell or distribute dietary supplements as part of their

practice. Minnesota Statutes, § 146A.01, subd. 4(a)(11) includes in the definition of OCAP practitioners those who engage in healing practices utilizing food, food supplements and nutrients. This means that practitioners will claim they are outside of OCAP's jurisdiction due to the federal law.

[3] Some OCAP practitioners use devices that appear to require regulation by the FDA under its medical device review, approval and classification system. Staff refer matters involving medical devices to the FDA for their review and consideration.

II. OCAP's Staff and Budget

A. Employees

July 1, 2002 to December 26, 2002, 1 FTE investigator and .25 FTE support staff person.
December 27, 2002 to April 2003, 0 FTE investigator.
April 2003 to June 30, 2003, 1 FTE investigator.
July 1, 2003 to March 31, 2004, .50 FTE investigator.
April 1, 2004 to June 30, 2004, 1 FTE investigator.

B. Receipts and Disbursements and Major Fees Assessed By Office

The OCAP is part of the Health Occupations Program within the Health Policy, Information and Compliance Monitoring Division in the Minnesota Department of Health. The program is funded by the General Fund. There are no credentialing components to the OCAP, therefore no fee-based revenue exists. In FY 2003 and 2004, there were no final civil penalties assessed.

Civil Penalties Received		Expenditures	
FY 2003	\$0	FY 2003	\$ 32,028
FY 2004	\$0	FY 2004	\$ 1, 304
		TOTAL	\$ 33,332

III. Licensing and Registration

There are no licensing or registration activities to this Office.

IV. Complaints

A. Complaints Received

	<u>FY 2003</u>	<u>FY 2004</u>
Complaints Received	22	18
Complaints Per 1,000 Regulated Persons (Estimated 3,000 practitioners)	7.26	5.94

Complaints by Type of Complaint

	<u>FY 2003</u>	<u>FY 2004</u>
Sexual Misconduct	6	10
Impaired Objectivity	0	0
Harm to Public/Client ¹	9	5
Failure to Provide Referral ²	2	0
Misrepresentation of Credentials	3	1
False Advertising	1	0
Other Disciplinary Action Taken	1	1
Bartering	0	1

B. Open Complaints on June 30

	<u>FY 2003</u>	<u>FY 2004</u>
Total Number of Open Complaints	25	37
Open Less than three months	5	1
Open 3 to 6 months	2	6
Open 6 to 12 months	15	11
Open more than 1 Year (explain) ³	3	19

C. Closed Complaints on June 30

	<u>FY 2003</u>	<u>FY 2004</u>
Number Closed	7	6
<u>Disposition By Type</u>		
A. Advisement	2	2
B. Dismissal	0	4
C. Referral to Licensing Boards/Other Agency	4	0
D. Granted Permission to Practice	1	0

¹“Harm to the Public” constitutes conduct by a practitioner likely to deceive, defraud, or harm the public; or demonstrating a willful or careless disregard for the health, welfare, or safety of a client; 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. This would include unsafe services and puncture of the skin.

²“Failure to Provide Referral” is defined as failure by the unlicensed complementary and alternative practitioner to provide a client with a recommendation that the client see a health care provider who is licensed or registered by a health-related licensing board or the commissioner of health, if there is a reasonable likelihood that the client needs to be seen by a licensed or registered health care provider”.

³Explanation of cases open for more than one year: The OCAP had one full time investigator between July 1, 2002 and December 26, 2002. The investigator position was left vacant after December 2002, and the Department did not fill the vacancy because of limited General Fund dollars. The Section reassigned an existing staff person so that there was one FTE staff from April 2003 through June 2003 and thereafter, there was one-half time investigator from July 2003 to March 2004 to conduct all of the investigative, enforcement and clearinghouse activities. Fluctuating levels of staffing meant that a backlog of investigations was created during this time. A full-time investigator was hired on March 31, 2004. Investigations are very time consuming. Factors contributing to time taken in investigations include investigating to determine whether jurisdiction exists, numbers of witnesses, the time client-victims take in deciding to cooperate fully with the Department, and practitioner non-cooperation.

V. Trend Data as Of June 30

<u>Fiscal year</u>	<u>Complaints Rec'd</u>	<u>Complaints Per 1,000</u>	<u>Open Complaint Files</u>
FY 2004	18	5.94	37
FY 2003	22	7.26	25
FY 2002	16	5.28	8
FY 2001	1	.33	1
FY 2000	0	0	0