

**Office of Unlicensed Complementary and Alternative Health Care Practice
Minnesota Department of Health
Biennial Report
July 1, 2004 to June 30, 2006**

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 interviews and 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 and complainants.
- 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 information about practitioner responsibilities, consumer legal rights, types of alternative and complementary practices, and information about other relevant state and federal regulatory agencies.

- Being available by telephone, e-mail 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

- During the biennium, OCAP completed 12 enforcement actions against practitioners. Seven of the enforcement actions were against massage therapists for sexual misconduct.
- In the 2005 legislative session, there was a bill proposing repeal of OCAP effective July 1, 2005. OCAP's full-time investigator left in April 2005 due to the possible repeal. The proposed repeal changed the priorities for OCAP and new complaints received in the first half of calendar year 2005 were de-prioritized in order to complete existing investigations and enforcements. When the repeal did not pass, OCAP regained a full-time investigator in July 2005. This event caused a disruption in OCAP's ability to conduct all its activities fully from January 2005 to June 2005.
- OCAP continued to work with its medical consultant physician until 2005 when the physician could not continue to work for OCAP without fees and the OCAP did not have funds for that arrangement. Instead, the OCAP worked with a Registered Nurse within the Department to assist OCAP on a case involving alleged diagnoses of medical conditions and medically related topics.
- OCAP developed and maintained a collaborative relationship with the local office of the Federal Food and Drug Administration (FDA) in July 2005. The FDA was very active in assisting OCAP in reviewing medical device labeling in a specific case. OCAP and the FDA do not have overlapping jurisdictions, and such collaboration is necessary in order to be efficient and effective. This relationship is continuing and ongoing for other OCAP matters.
- In the fall of 2005, OCAP was one of five occupational groups regulated by the Health Occupations Program (HOP) in the Department included in a seven-month project to develop a comprehensive database. By the end of June 2006, the database was in the final stages of testing and working well.
- In January to March 2006, local FOX TV Channel 9 news conducted an investigation about a complementary and alternative health care practitioner and highlighted the OCAP in its televised report.

- During the biennium, OCAP revised its website to include better consumer and practitioner information. The added information includes names of all disciplined practitioners and links to relevant federal and state regulatory agencies for information about OCAP practices, dietary supplements and medical devices.
- The OCAP received over 300 inquiries from both practitioners and consumers. The OCAP mailed out over 625 brochures/information packets/copies of disciplinary actions.

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

- Complementary and alternative health care modalities continue to be a widely accepted and accessed option for health care consumers in Minnesota and across the nation. There is need for continuing regulatory oversight.
- Massage therapists have sought licensing or registration by the state. However, massage therapists have not been able to agree on the minimum educational and training qualifications for a credential, and for this reason, bills to establish state regulation have failed. Some cities license massage therapists, but except for OCAP, a statewide authority to sanction illegal conduct does not exist in Minnesota.
- There remain a significant number of sexual misconduct and boundaries issues in massage therapy. During this period, OCAP took disciplinary action against seven massage therapists for sexual misconduct and boundaries issues. Of these, three were also charged with criminal sexual conduct by law enforcement. The range of educational background for these disciplined massage therapists is from informal massage therapy training to graduating from a massage therapy program with over 700 hours of training.
- The OCAP identified a problem with OCAP practitioners who are illegally using restricted medical devices as defined by the FDA. The FDA only has jurisdiction over medical device manufacturers and the labeling of medical devices. Class II and III medical devices are restricted and cannot be used by unlicensed health care practitioners; however numerous OCAP practitioners are using restricted medical devices illegally.

II. OCAP's Staff and Budget

A. Employees

July 1, 2004 to April 12, 2005, 1 FTE investigator.

From April 13, 2005 to June 30, 2005, 0 FTE investigator.

From July 1, 2005 to June 30, 2006, 1 FTE investigator.

B. Receipts and Disbursements and Major Fees Assessed By Office

The OCAP is part of the Health Occupations Program within the 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.

| Civil Penalties Received | | Expenditures | |
|---------------------------------|----------------|---------------------|-------------------|
| FY 2005 | \$4,425 | FY 2005 | \$ 47,491 |
| FY 2006 | \$ 705 | FY 2006 | \$ 67,343 |
| TOTAL | \$5,130 | TOTAL | \$ 114,834 |

III. Licensing and Registration

There are no licensing or registration activities in OCAP.

IV. Complaints

A. Complaints Received

| | <u>FY 2005</u> | <u>FY 2006</u> |
|---------------------------------------------------------------------------|----------------|----------------|
| Complaints Received | 14 | 14 |
| Complaints Per 1,000 Regulated Persons (Estimated 2,700 practitioners) | 5.18 | 5.18 |

| Complaints by Type of Complaint | <u>FY 2005</u> | <u>FY 2006</u> |
|----------------------------------------|----------------|----------------|
| Sexual Misconduct | 3 | 2 |
| Impaired Objectivity | 0 | 1 |
| Harm to Public/Client ¹ | 3 | 9 |
| Misrepresentation of Credentials | 2 | 1 |
| False Advertising | 1 | 0 |
| Other Disciplinary Action Taken | 1 | 0 |
| Criminal-personal or OCAP related | 2 | 0 |
| Failure to furnish records | 1 | 0 |
| Failure to provide bill of rights | 1 | 0 |

| | | |
|----------------------------------------------|-----------------------|-----------------------|
| Failure to follow Commissioner's order | 0 | 1 |
| Failure to refer ² | 0 | 0 |
| B. Open Complaints on June 30 | <u>FY 2005</u> | <u>FY 2006</u> |
| Total Number of Open Complaints | 37 | 34 |
| Open Less than three months | 1 | 4 |
| Open 3 to 6 months | 6 | 5 |
| Open 6 to 12 months | 11 | 5 |
| Open more than 1 Year (explain) ³ | 19 | 20 |
| C. Closed Complaints on June 30 | <u>FY 2005</u> | <u>FY 2006</u> |
| Number Closed | 17 | 15 |
| <u>Disposition By Type</u> | | |
| A. Dismissed | 9 | 5 |
| B. Revoked | 5 | 4 |
| C. Suspended/Restricted Practice | 2 | 1 |
| D. Advisement/Warning Letter | 1 | 3 |
| E. Referred to other Board/Agency | 0 | 2 |

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: There are multiple factors contributing to a case backlog in OCAP. During the biennium, there was only one FTE investigator position funded and no support staff, so the investigator position also handled the support work, including all intake calls and communications. Further, the OCAP investigator position was vacant between April 13, 2005 and June 30, 2005. Also, as explained in this report, between January 2005 and June 2005, and due to the proposed repeal of OCAP, OCAP priorities shifted to completing existing investigations and enforcements instead of handling new investigations. Finally, the OCAP investigations are very time consuming because legal jurisdiction must be established, many of the legal issues presented are novel and most of the cases allege very serious misconduct.

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 2006 | 14 | 5.18 | 34 |
| FY 2005 | 14 | 5.18 | 37 |
| 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 |