Office of Unlicensed Complementary and Alternative Health Care Practice

Report to the Sunset Advisory Commission

Minnesota Department of Health

December 2011

MINNESOTA MDH DEPARTMENT OF HEALTH

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As requested by Minnesota Statute 3.197; this report cost approximately $1,950 to prepare, including staff time, printing and mailing expenses.

I. Executive Summary

The information in this report is provided in response to the Sunset Advisory Commission's report requirements and describes how the Office of Unlicensed Complementary and Alternative Health Care Practice (OCAP) protects consumers of services provided by complementary and alternative health care practitioners.

OCAP is a consumer protection activity conducted within the Minnesota Department of Health. Though included in the definition of a health-related licensing board OCAP does not license practitioners, and it is not a board. OCAP is unique among occupational regulatory agencies as it does not limit the constitutional right of any person to engage in the provision of any alternative and complementary health care service not otherwise restricted by existing health-related occupational regulations. OCAP regulates by investigating complaints and conducting an information clearinghouse for consumers and practitioners.

The 2011 OCAP fiscal year budget was $74,000 and is entirely general fund supported. The office has one 0.75 FTE staff person and operates without administrative support staff.

OCAP practitioners include persons who provide massage therapy, homeopathy, traditional naturopathy, herbology, healing practices utilizing food, food supplements and nutrients, healing touch, Reiki and other practices that may fall within OCAP jurisdiction. These activities are not defined in statute and the practitioners are not subject to any education, training or examination requirements, do not have any recognition or specific authorization from the state to practice and are not listed on a roster of practitioners who provide complementary and alternative health care services. Practitioners are identified by the OCAP when a complaint is received or the office has learned of a possible violation of any one of twenty-three prohibited acts established in statute. OCAP protects consumers by holding unlicensed alternative and complementary health care practitioners accountable to business and ethical standards of conduct such as professional boundaries, client privacy, and accurate and full disclosure of any training or education, use of titles, services provided and of fee schedules.

II. Statutory Requirements

1. The efficiency and effectiveness with which the agency or the advisory committee operates.

The efficiency and effectiveness with which the OCAP operates is monitored through regular management reports of numbers of inquiries, investigations opened and closed, types of allegations made, and enforcement actions opened and closed. All investigative and enforcement activity is prioritized based on type of allegation so that the most egregious conduct, e.g., sexual activity, is addressed ahead of less serious matters such as misleading advertising. Finally, regular review of open files assures investigations are completed and closed appropriately. Given the size of the office and no means of identifying practitioners or consumers other than by inquiries and complaints, a summary of activities best describes how the OCAP uses its resources:

- On average, the OCAP receives over 270 inquiries annually from consumers, practitioners, law enforcement, other agencies and interested persons. The most common inquiries are information about existing laws and those practices that may be considered complementary and alternative health care.

- On average, the OCAP receives 16 written complaints annually with 67% of complaints being related to sexual misconduct or other client/public harm.

- The OCAP has opened 146 investigations since inception in 2001 and currently has 24 open investigations. The opening of an investigation is dependent upon the receipt of a written complaint form or OCAP learning of a violation from another agency or information source.

- The OCAP has completed 23 public disciplinary enforcement actions (16% of investigations opened). A disciplinary enforcement action is commenced when the department determines that a violation of statute has been established and through a Stipulation and Consent Order or Determination, the practitioner agrees to disciplinary action. Disciplinary enforcement actions may include the suspension or revocation of the right to practice, additional education or training, an order to cease using restricted or unapproved medical devices, or any other action deemed necessary by the Commissioner of Health. Any of these actions may also include a civil penalty.

- 70% of OCAP public disciplinary enforcement actions have been related to sexual misconduct by massage therapists. 44% of these investigations had previous law enforcement investigation and prosecution resulting in a conviction; however, these practitioners were not prohibited by the court from continuing to provide complementary and alternative health services, and without OCAP action would not have been barred from future massage practice.

- 56% of OCAP investigations related to sexual misconduct by massage therapists that resulted in OCAP public disciplinary enforcement action were not prosecuted as a criminal offense because the threshold for criminal prosecution was not met. In one situation, the massage therapist was found not guilty of criminal sexual conduct after being adjudicated mentally incompetent. Without the OCAP investigation and public action, these practitioners would not be prohibited or restricted in their practices and would pose a continued threat of future public harm.

- The OCAP maintains a website where interested persons may view information relevant to complementary and alternative health care; the website provides links to federal agencies and other websites related to complementary and alternative practices. The OCAP website also contains a list of Minnesota OCAP practitioners against whom the Commissioner has taken disciplinary action. The list of disciplined practitioners is linked to the public document, either a Determination or Stipulation and Consent Order, which describes the prohibited conduct and discipline imposed.

The overall efficiency and effectiveness of the OCAP has been hindered by intermittent availability of staff and unallotment of funding. Specifically:

- Though established in July 2001, a near shutdown of government and a subsequent employee strike prevented hiring staff for OCAP until midway through the first fiscal year. OCAP staff was first hired in March 2002.
- From January 2003 through most of FY 2004, the OCAP had no or reduced investigator staff. Beginning in FY 2004 through FY 2007 OCAP had one FTE investigator.
- Beginning in FY 2008 the OCAP was staffed at .9 FTE until September 2009 when the OCAP ceased operations due to unallotment. The legislature restored funding in FY 2011 and OCAP has conducted its activities with one investigator at .75 FTE since that time.

These interruptions in staffing and funding negatively impacted ongoing operation by suspending investigation, enforcement and public information activities. Despite the uneven staffing, the OCAP

has frequently received comments from other licensing and law enforcement agencies and consumers as to the helpfulness of the OCAP in providing assistance and information.

2. Identification of the mission, goals, and objectives intended for the agency or advisory committee and of the problem or need that the agency or advisory committee was intended to address and the extent to which the mission, goals, and objectives have been achieved and the problem or need has been addressed.

The legislature enacted OCAP in Minnesota Statutes, section 146A.02, Subdivision 1 to:

- Receive and investigate complaints against unlicensed complementary and alternative health care practitioners and take enforcement action for violations of prohibited conduct and monitor compliance with enforcement actions. Statistical information provided in #1 describes activities of investigation and disciplinary enforcement actions.

- Respond to over 270 inquires annually by serving as a clearinghouse to inform and educate consumers and practitioners about OCAP laws and the dissemination of objective information including what is prohibited conduct and the requirement that each consumer receive a Client Bill of Rights from the OCAP practitioner. Among other things, the Client Bill of Rights provides consumers with information about the background and training of the OCAP practitioner and notice that the practitioner is not licensed by the state and may not make a medical diagnosis.

Complementary and alternative health care practices have increased greatly in Minnesota and the United States. According to a 2007 survey, The National Institutes of Health Center for Complementary and Alternative Medicine reports that 38% of all adults use complementary and alternative health care services. By telephone, email and website the OCAP is an information clearinghouse providing the public, practitioners, and other interested persons with information resources about the regulation of complementary and alternative health care practices in Minnesota. The website includes topical alternative medicine links as well as links to the federal Food and Drug Administration, Federal Trade Commission and other health related licensing boards and agencies in Minnesota.

3. Identification of any activities of the agency in addition to those granted by statute and of the authority for those activities and the extent to which those activities are needed.

There are no activities conducted by the OCAP that are not granted by statute.

4. Assessment of authority of the agency relating to fees, inspections, enforcement, and penalties.

The OCAP has the authority to assess penalties and fees as provided in the Disciplinary Actions section of Minnesota Statutes, 146A.09, subdivision 1, (4)(6). The purpose of these penalties and fees are to deprive a violator of any economic advantage gained by engaging in the violation and/or to reimburse the OCAP for costs of the investigation and any subsequent proceeding. The OCAP has assessed and collected $6,563 in penalties since inception: $2,358 from four practitioners for sexual misconduct; $3,500 from one practitioner for client harm/blood cell analysis; $705 from one practitioner for client harm/medical device use.

5. Whether less restrictive or alternative methods of performing any function that the agency performs could adequately protect or provide service to the public.

Since the OCAP has no licensure or registration requirements it is arguably the least restrictive means of public protection. For example, it does not have authority to impose professional standards of practice or define scopes of practice for the various modalities; and it does not provide any type of credential to alternative and complementary practitioners. Alternatively, regulation could include licensure or registration of practitioners; however, this would be a more restrictive and costly means of regulation and likely ineffective for several reasons. Established and accepted definitions of modalities used and functions performed in alternative and complementary practices must exist in order to recognize an "occupation" and establish regulatory jurisdiction. A "job task analysis" identifying the knowledge and skills needed by persons to safely and competently use modalities and perform functions must be completed, and educational programs must be established and accredited to consistently train, educate and test persons seeking to enter the occupation. Community agreement on standards for qualifications to practice the occupation must be present for the legislature to enact regulation specifying how the regulatory agency will determine who may or may not practice and use occupational titles. All of these elements are precursors to government licensing, certification or registration of an occupation, and if not present, attempts to impose regulation will be frustrated and costly.

Repeal of Minnesota Statutes 146A would eliminate the OCAP activities but would also end any public protection provided by the OCAP. Public protection would not be provided by other agencies or health licensing boards as limits to their authorities extend their jurisdictions only to their licensees and defined scopes of practice. When a licensed practitioner works outside their defined scope of practice and provides OCAP services, the licensing board is unable to take action against their licensee and refers the complaint to the OCAP for investigation and enforcement.

6. Extent to which the jurisdiction of the agency and the programs administered by the agency overlap or duplicate those of other agencies, the extent to which the agency coordinates with those agencies, and the extent to which the programs administered by the agency can be consolidated with the programs of other state agencies.

The OCAP has no overlap with other state agencies or departments. It does, however, fill a gap in public protection for users of complementary and alternative health care services.

In a situation where the actions of a practitioner meet the threshold for criminal prosecution, the practitioner may be subject to criminal sanctions that could eliminate any public threat during a period of incarceration; however, their right to practice at a later date stays intact without additional action by the OCAP. The OCAP has made referrals to and receives contacts from law enforcement agencies, and it coordinates investigative activity with law enforcement to aid prosecution when possible.

The OCAP established and continues a collaborative working relationship with the local office of the Federal Food and Drug Administration (FDA). The FDA has jurisdiction over medical device use, labeling and marketing, and establishes a classification for medical devices used on human beings that manufacturers/marketers use to determine if the medical device is restricted in sales/use to licensed health care providers. Some OCAP practitioners use medical devices in their practice. The OCAP has found practitioners using both medical devices not FDA-approved for marketing in the United States and using medical devices that are restricted in use to licensed health care

providers. Although the OCAP and FDA share a common interest, they do not have overlapping jurisdiction as the FDA does not pursue enforcement against individuals but rather only the manufacturer/marketer of these devices.

The OCAP continues to have jurisdiction over traditional naturopathic practitioners; however, as of 2009 naturopathic doctors are now registered with the Minnesota Board of Medical Practice. This registration involves a small number of practitioners and has not substantially affected the activities of the OCAP as traditional naturopaths are not prohibited from practice because of the registration of naturopathic doctors.

7. The promptness and effectiveness with which the agency addresses complaints concerning entities or other persons affected by the agency, including an assessment of the agency's administrative hearings process.

Although the OCAP has consistently tried to be timely in initiating investigations and responding to inquiries or concerns, it has not always been successful. There are several factors that have limited the ability to initiate investigations as promptly as desired: 1) inconsistent funding and staffing; 2) prioritizing cases that involve sexual misconduct or other serious public harm; 3) unusual or novel practices by those regulated that require outside expert advice/testimony from a licensed health care provider.

The OCAPs funding is not adequate to pay for services from outside licensed professionals. In one situation, which included a case-conference hearing, the OCAP was able to obtain the voluntary expertise of a physician; however, at the conclusion of the case, the physician informed staff that he could no longer provide services without compensation.

When operations resumed following the period of unallotment in FY 2010, the OCAP had 46 investigations pending that were at least one year old. The OCAP has made significant progress since that time by reducing pending cases by 50%.

The OCAP has reached settlements in 96% of the cases where enforcement action was commenced and initiated one administrative hearing which has kept attorney general and administrative hearing costs low.

8. Assessment of the agency's rulemaking process and the extent to which the agency has encouraged participation by the public in making its rules and decisions and the extent to which the public participation has resulted in rules that benefit the public.

The OCAP relies solely on Minnesota Statutes 146A and has not undertaken any rulemaking. If it would be helpful or necessary to further define or clarify provisions of Chapter 146A, the OCAP would bring changes directly to the legislature because it is more cost effective than rulemaking.

9. The extent to which the agency has complied with federal and state laws and applicable rules regarding equality of employment opportunity and the rights and privacy of individuals, and state law and applicable rules of any state agency regarding purchasing guidelines and programs for historically underutilized businesses.

The OCAP operates within the guidelines established by MDH and complies with all MDH rules and procedures concerning these issues. These include administrative procedures in Chapter 13, data practices in Chapter 14 and MDH policies and procedures for hiring staff and purchasing goods and services.

10. The extent to which the agency issues and enforces rules relating to potential conflicts of interest of its employees.

The Department of Health includes conflict of interest provisions in its Code of Ethics policy and it conforms to the Statewide Code of Ethics: M.S. 43a.38; the Political Activities Law: M.S. 43a.32; and the Federal Hatch Act Lobbyist Law: M.S. 10a.07. OCAP conducts it activities consistent with these policies.

11. The extent to which the agency complies with chapter 13 and follows records management practices that enable the agency to respond efficiently to requests for public information.

The OCAP operates within MDH guidelines for compliance with chapter 13 except where exempted from the data practices requirements applicable to licensing agencies in section 13.41. The OCAP responds promptly to all requests for public information as required by chapter 13, and maintains data privacy on individuals consistent with the requirements in Minnesota Statutes, section 146A.06 subdivision 2.

12. The effect of federal intervention or loss of federal funds if the agency is abolished.

The abolishment of the OCAP would have no effect on federal intervention or funding.

13. A priority based budget.

The OCAP is general funded with a budget appropriation of $74,000 that provides for supplies and expenses and one .75 staff person who performs the following statutorily-directed activities:

OCAP Activity	.75 FTE	$74,000 Budget
Receive, investigate complaints	.50	$30,000
Take enforcement action	.20	$12,000
Clearinghouse: Answer consumer & practitioner inquiries	.30	$18,000
Supplies & Expenses:		
Printing/Duplication		$500
Professional Services		$2,000
Enforcement Activities		$3,000
Communications		$500
Travel		$500
Supplies		$500
Attorney General Costs		$4,000
Computer Equip/Services		$1,000
IT Developer Services		$2,000
Subtotal		$14,000

III. Other Requirements

1. OCAP Organizational chart.

See Appendix A showing the position of OCAP in the Health Occupations Program in the Compliance Monitoring Division in the Policy, Quality & Compliance Bureau in the Minnesota Department of Health.

2. Link to the OCAP Website:

http://www.health.state.mn.us/divs/hpsc/hop/ocap/index.html

3. and 4. Six year history of OCAP full time equivalent staffing levels and funding.

FY	FTE'S	GF APPROPRIATION
2005	1.0	$112,000
2006	1.0	$ 65,000
2007	1.0	$ 65,000
2008	0.9	$ 73,880
2009	0.9	$ 80,750
2010*	0.17	$ 12,248
2011	0.75	$ 74,000

*The OCAP was not operational September 1, 2009 through June 30, 2010 due to unallotment.

5. A list of all advisory councils whose primary function is to advise the organization.

The OCAP does not have advisory councils.

6. Citation of the statute creating the organization and to other statutes governing or administered by the organization.

Minnesota Statutes:

- 146A.02 creates the OCAP to investigate complaints and take disciplinary action and serve as a clearing house on complementary and alternative health care practices through dissemination of objective information;
- 146A.01, subd. 3 identifies that a client is an individual who receives services from a complementary and alternative health care practitioner;
- 146A.01, subd. 4 (a) identifies complementary and alternative health care practitioners;
- 146A.08, subd. 1 identifies prohibited conduct of complementary and alternative health care practitioners;
- 146A.09, subd. 1 (1-7) identifies the types of disciplinary actions the Commissioner of Health may initiate when there is a violation of law;

- 146A.09, subd. 1 (4) (6) identifies penalties/fees the commissioner may impose when a practitioner engages in prohibited conduct;

- 148A.11 identifies the information a practitioner must include and disseminate in their Client Bill of Rights.

7. Citation to the administrative rules adopted by the organization.

The OCAP has not adopted administrative rules.

8. A copy or link to any other governance documents adopted by the organization.

The OCAP has not adopted any other governance documents.

Appendix A

MINNESOTA MDH DEPARTMENT OF HEALTH

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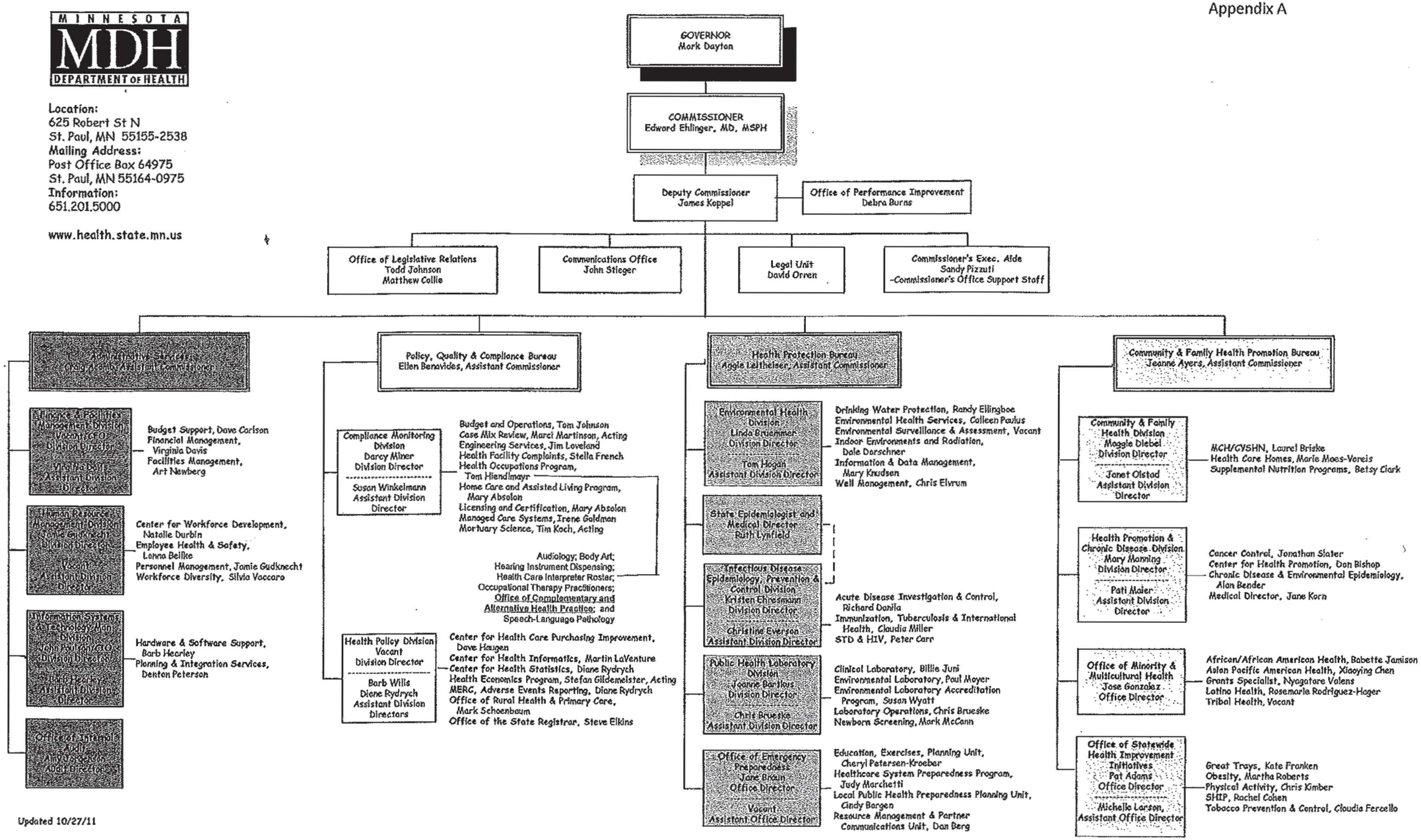

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