Minnesota Department of Health Comments to the
2009 Genetic Information Report

Introduction. The Minnesota Department of Health (MDH) thanks Commissioner of Administration, Dana Badgerow, and her staff and the members of the Genetic Information Work Group for their hard work, dedication, and thoughtful insights that went into the preparation of the 2009 Genetic Information Report. The topic of genetic information is extremely complex and nuanced and is rapidly evolving in response to rapid scientific progress.

MDH's mission is to protect, maintain, and improve the health of all Minnesotans. In order to carry out its mission, MDH collects a great deal of health information and many human biological specimens. MDH has always carefully protected privacy of this information and these specimens. MDH has always been an advocate of strong legal privacy protections.

MDH collects many types of health information:

- MDH collects health information so we can detect outbreaks at their earliest stages and so we can respond quickly and effectively to control the outbreaks and to learn how to prevent or minimize future outbreaks.
- MDH conducts inspections and surveys of nursing homes to ensure that vulnerable patients are protected.
- MDH responds to complaints about health care facilities and conducts investigations, as necessary.
- MDH collects data on birth defects so we can better understand and prevent the 70% of birth defects where the cause is unknown.
- MDH collects information on every case of cancer in Minnesota in order to continue the improvement in cancer prevention, diagnosis, and treatment which will continue the impressive gains in the battle against cancer. Note that the information collected on all cancers was instrumental in MDH determining that there was an unusually high occurrence of mesothelioma in northeastern Minnesota. This has lead to an in-depth study to determine the cause.
- MDH uses information and specimens to continuously improve the newborn screening program, which currently finds approximately 140 babies a year with serious, but treatable conditions, thereby saving lives or preventing serious disability.
- MDH collects and uses health information and specimens for many other specific programs, all directed at protecting, maintaining, and improving the health of all Minnesotans.

MDH protects health information in many ways:

- MDH has a culture of respect for and protection of the confidentiality of health records.
- In addition, when MDH has to use or disclose health information to protect the public's health, we disclose only as permitted by law and then only the minimum necessary and only to those with a need to know.
- MDH provides data practices training to staff, along with continuing education on a monthly basis to all staff about data privacy and data security.
- MDH has a Data Practices Coordinator available to all staff for consultation on data privacy issues.
- In summary, MDH uses health information legally and respectfully and only on a need to know basis and we carefully protect the information from disclosure outside of MDH.

Almost all health information has a genetic component, whether it is a specific genetic condition or a genetic host factor that affects how a person is susceptible to or able to recover from an infection or how a person's body is able to process toxins or chemicals found in the environment.

MDH needs continued access to all types of health information, including genetic information and human biological specimens, in order to continue to fulfill its mission to protect, maintain, and improve the health of all Minnesotans.

Executive Summary. The main points of MDH's response to the draft 2009 Genetic Information Report are:

=> MDH supports privacy protections for human biological specimens, but encourages more study into what the protections should be and how to avoid unintended consequences when putting protections into place.

=> MDH needs exceptions to the genetic privacy statute (Minnesota Statutes, section 13.386) in order to carry out its responsibilities to protect public health and for health oversight activities related to health care providers licensed or otherwise regulated by MDH. These exceptions would be similar to the exceptions for MDH that exist to health information privacy statutes.

=> MDH agrees with the draft report recommendation to amend the Minnesota Cancer Surveillance System (MCSS) statutes to give the patient (as opposed to the patient's physician) the right to decide if relatives can be interviewed by MCSS for an epidemiologic investigation.

=> MDH agrees with the draft report recommendation that the data subject of a third generation pedigree is the individual who provided the information.

=> MDH supports clarifying that the data subject is the individual from whom the genetic information is collected. MDH also supports the other clarifications recommended in the draft report. These clarifications would make the genetic privacy statute more workable.

=> MDH has many concerns about expanded Tennessen Warning requirements related to the collection of genetic information and human biological specimens.

Privacy Protections for Specimens.

The draft report recommended that the protections for health data be extended to human biological specimens. The draft report noted specifically that these health privacy protections included those in the HIPAA Privacy Rule, the MN Health Records Act, and medical and health data under the Data Practices Act.

MDH agrees in concept with this recommendation. Protections for the privacy of specimens are important, but significantly more study has to be done before extending data privacy protections to specimens. More harm than good can come from acting without sufficient forethought to avoid unintended consequences.

Things to consider in any privacy protections for specimens are the important differences between data and specimens. Data can be copied and redacted; specimens generally cannot be copied or redacted. Specimens are physical property; media that data are stored on are physical property, but the data themselves are generally not physical property. These important differences were not addressed in the draft report and need to be considered before passing any legislation.

Public Health Exceptions to the Genetic Privacy Statute.

All three systems of privacy protection for health related data mentioned in the draft report are extensive in their detail. For each of these systems of data privacy protections, there are many necessary exceptions that are thoughtfully and carefully crafted to protect the public. For example:

- The Minnesota Health Records Act includes seven pages to define the protections for health records held by Minnesota health care providers and patient rights to those records.
    - For the Minnesota Health Records Act, MDH is required to develop a notice of disclosures of health records that may be made without the written consent of the patient. MDH has developed a one-page document that can be used by providers to give patients this notice. MDH has also prepared a list with a one or two sentence summary of the disclosures and the conditions necessary for a provider to make the disclosures, along with the statutory citation. This list is nine pages long.
- The Minnesota Government Data Practices Act includes 120 pages to define privacy protections for government data in Minnesota. This is in addition to many other privacy references distributed throughout other chapters of Minnesota Statutes.
    - Exceptions or special conditions are found in many places in the Data Practices Act.
- The federal HIPAA Privacy Rule includes at least 40 pages to define the core of the federal privacy protections for protected health information (PHI), along with references to many other pages of text that create definitions, describe federal preemption, and set out penalties for violations.
    - Specific exceptions to these privacy protections are the public responsibility exceptions to the HIPAA Privacy Rule. In 45 Code of Federal Regulations, section 164.512, there are 12 public responsibility exceptions that allow the disclosure of PHI without patient authorization. Among these 12 exceptions are three that permit health care providers and health plans to disclose PHI to MDH and to other public health authorities and health oversight agencies. These include:
        - Uses and disclosures required by law.
        - Uses and disclosures for public health activities.
        - Uses and disclosures for health oversight activities.
        - Note that the text of the applicable portions of the HIPAA Privacy Rule is included at the end of these comments.

The bottom line is that privacy is very important, but for society to operate, it is necessary to have many thoughtfully crafted exceptions.

These exceptions to patient consent or authorization are essential for MDH to gather and use the data necessary to protect public health and conduct health oversight activities.

Similarly, it is essential that there be exceptions to genetic privacy protections in order to allow MDH to gather and use the genetic information necessary to protect public health and conduct

health oversight activities.

To accomplish this, MDH suggests that the Minnesota Genetic Privacy Statute be amended in subdivision 3 as follows:

"Subd. 3. **Collection, storage, use, and dissemination of genetic information.** (a) Unless otherwise expressly provided by law, genetic information about an individual:

(1) may be collected by a government entity, as defined in section 13.02, subdivision 7a, or any other person only with the written informed consent of the individual;

(2) may be used only for purposes to which the individual has given written informed consent;

(3) may be stored only for a period of time to which the individual has given written informed consent; and

(4) may be disseminated only:

(i) with the individual's written informed consent; or

(ii) if necessary in order to accomplish purposes described by clause (2). A consent to disseminate genetic information under item (i) must be signed and dated. Unless otherwise provided by law, such a consent is valid for one year or for a lesser period specified in the consent.

(b) Unless otherwise expressly provided by law, the Department of Health is exempt from paragraph (a) as follows:

(1) for collecting, using, storing and disseminating genetic information as required by law;

(2) for public health activities that include collecting, using, storing, and disseminating genetic information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions;

(3) for collecting, using, storing, and disseminating genetic information for health oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of the health care system and entities subject to governmental regulatory programs for which genetic information is necessary for determining compliance with program standards."

Minnesota Cancer Surveillance System (MCSS)

In response to a legislative directive, the draft report made the recommendation to amend the MCSS statute to require MDH to obtain consent from patients for all interviews. The draft report also recommended removing the requirement that MDH obtain consent from the attending physician to conduct interviews with patients or their relatives.

MDH agrees with this recommendation. It has been MDH's practice to seek the consent of the patient, unless the patient is incapacitated, so this recommendation would be consistent with MDH's current practice.

The draft report made a second recommendation on who could give consent on behalf of the patient when the patient is incapacitated. The draft report recommended a hierarchy of individuals who would be authorized to give consent in this situation. The hierarchy is:

1) Legal Guardian
2) Health Care Agent
3) Spouse or Registered Domestic Partner

4) Next of Kin
5) Personal Representative

MDH agrees with this recommendation to determine which person can give consent on behalf of the patient for interviews.

MDH has several other concerns:
1) MDH may need to contact relatives to find out if there is a legal guardian or health care agent.
2) It may be important for MDH to consult with the patient's physician for several reasons:
    a) to see if the patient is well enough to be interviewed;
    b) to help explain the interview and its purpose to the patient; and
    c) to see if patient is an appropriate subject for the interview.
3) The term "incapacity" is not defined. The patient's privacy is protected by the hierarchy of consent proposed in the draft report, so MDH urges the Commissioner of Administration to recommend that MDH determine when a patient is incapacitated.

MDH recommends further amendments to Minnesota Statutes, section 144.69, as follows:

=> The last sentence of paragraph (b) should have language added to the recommendation of the draft report to say: "If the patient is deceased, or <u>if the commissioner determines that the patient is</u> unable to provide consent, consent must be obtained from the patient's:"

=> Renumber paragraph (d) as paragraph (f).

=> Add a new paragraph (d) that says: "<u>With the approval of the commissioner, the department may contact the spouse, registered domestic partner, next of kin, or physician of the patient to learn if the patient has a legal guardian or health care agent.</u>"

=> Add a paragraph (e) that says: "<u>The department may consult with the patient's physician to learn if the patient is well enough to be interviewed, to ask for the physician's help in explaining the interview and its purpose to the patient and to see if patient is an appropriate subject for the epidemiologic investigation.</u>"

Third generation pedigree.

The draft report recommends that the patient providing information for a three-generation pedigree is the data subject. The draft report also recommends that there not be greater access to pedigrees maintained at MDH than to pedigrees maintained by other government entities and private medical providers.

MDH agrees with these recommendations. Clarifying that the patient who provides information is the data subject will make this public health tool and health care tool workable.

The draft report suggests language to amend Minnesota Statutes, section 13.384, to make this the law for public sector medical providers. The department suggests adding language to section 13.3805 to make this the law for health data held by the department.

=> Add a new subdivision 5 that says: ""Three generation pedigree" means a pictorial representation or narrative of family health history given by an individual, including the names of other family members and their relationship to the individual. A three generation pedigree does not include the results of any tests from the family member's medical record. A three generation pedigree is health data about the individual. The individual is the data subject of the pedigree and has access to all of the data in the pedigree."

Clarification of the genetic privacy statute.

The draft report makes several recommendations for clarifying the genetic privacy statute, Minnesota Statutes, section 13.386. These include defining the data subject of genetic information and human biological specimens to be the individual from whom the information or specimens are collected. These also include six other clarifications.

MDH supports these clarifications. It has been over two years since section 13.386 was passed. Based on experience in working with the law, it has become apparent that these clarifications are needed.

Tennessen Warning for collection of genetic information and human biological specimens.

The draft report recommended extending Tennessen Warning requirements in the Data Practices Act to the collection of human biological specimens by government entities. The draft report recommended that a Tennessen Warning have additional requirements when genetic information and human biological specimens are collected:

- known secondary uses both internally and externally;
- the fact that any genetic information can share information about a person's blood relatives;
- if a Tennessen Warning notice describes a use for "research," it should describe any research that is in addition to a particular genetic condition; and
- how long the genetic information and / or specimens will be maintained.

The draft report also discussed the possibility of adding Tennessen Warning requirements when other persons collect genetic information and biological specimens and then submit these to a government entity.

MDH has many concerns about the recommendation for expanded Tennessen Warning requirements and the additional discussion of requiring a Tennessen Warning when someone other than the government entity collects the information or specimen.

Almost all health related information is also genetic information.

- Some health information is about specific condition caused by a single gene. This type of health information is clearly genetic information.
- Advances in science have increased our understanding of genetic components in many health conditions. Heart disease and diabetes are two health conditions with strong genetic components. These types of health information are also genetic information.
- There is evidence that there are host genetic factors in how people are susceptible and respond to some infectious diseases. We believe that this may be true for all or most infectious diseases. There are also host genetic factors in how people are affected by toxins and other substances in

the environment. So, even health information about infectious diseases and environmental pollutants might be considered genetic information.

What this means is that any expanded Tennessen Warning requirements for genetic information would apply to almost everything collected by MDH.

The Tennessen Warning is only a workable requirement when the government entity is asking an individual to supply private or confidential data about that individual. For example, when MDH interviews a person with a reportable communicable disease to determine how the disease was spread and whether the treatment has been effective, we give a Tennessen Warning and use the data consistent with the Tennessen Warning.

The Tennessen Warning is not workable when the government entity is collecting data about an individual from someone who is not the individual. For example, when a lab tests a specimen referred by a doctor for diagnosis and the lab determines an individual has a reportable communicable disease, the lab is required to report to MDH and in some cases send a specimen. Because MDH does not have direct contact with the individual, MDH cannot give the individual a Tennessen Warning. Further, the consequences of not giving a required Tennessen Warning are that MDH would not be able to use the information or specimen. MDH would be unable to protect public health if MDH was prohibited from using disease information or specimens.

Likewise for genetic information and human biological specimens, the Tennessen Warning would only be a workable requirement when the government entity asks an individual to supply information or specimens from that individual.

Specifically, a Tennessen Warning requirement would not be workable for the reporting of communicable diseases or related specimens or for the collection of many other types of public health data or specimens. There may be other privacy protections or some sort of modified Tennessen Warning, but they would have to be tailored to balance MDH's responsibility to protect public health with the individual's privacy. The goal would be to maximize public health protections while minimizing any intrusion on personal privacy.

When MDH directly collects an individual's specimen from that individual, MDH supports a Tennessen Warning. However, MDH does not support a Tennessen Warning under other circumstances that would inhibit our ability to protect public health.

=-=-=-= Public Responsibility Exceptions to HIPAA that Affect MDH =-=-=-=

"§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required. A covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) *Standard: Uses and disclosures required by law.*

(1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

. . .

(b) *Standard: uses and disclosures for public health activities.*

(1) *Permitted disclosures.* A covered entity may disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

. . .

(d) *Standard: Uses and disclosures for health oversight activities.*

(1) *Permitted disclosures.* A covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:

(i) The health care system;

(ii) Government benefit programs for which health information is relevant to beneficiary eligibility;

(iii) Entities subject to government regulatory programs for which health information is

necessary for determining compliance with program standards; or

(iv) Entities subject to civil rights laws for which health information is necessary for determining compliance.

(2) *Exception to health oversight activities.* For the purpose of the disclosures permitted by paragraph (d)(1) of this section, a health oversight activity does not include an investigation or other activity in which the individual is the subject of the investigation or activity and such investigation or other activity does not arise out of and is not directly related to:

(i) The receipt of health care;

(ii) A claim for public benefits related to health; or

(iii) Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.

(3) *Joint activities or investigations.* Notwithstanding paragraph (d)(2) of this section, if a health oversight activity or investigation is conducted in conjunction with an oversight activity or investigation relating to a claim for public benefits not related to health, the joint activity or investigation is considered a health oversight activity for purposes of paragraph (d) of this section.

. . . ."