DEPARTMENT OF HEALTH

Relevant Provisions of the Data Practices Act

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January 9, 2002

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Minnesota Government Data Practices Act

13.02 Definitions

Subd. 7. Government data

"Government data" means all data collected, created, received, maintained or disseminated by any state agency, political subdivision, or statewide system regardless of its physical form, storage media or conditions of use.

Subd. 15. Public data on individuals

"Public data on individuals" means data which is accessible to the public in accordance with the provisions of section 13.03.

Subd. 12. Private data on individuals

"Private data on individuals" means data which is made by statute or federal law applicable to the data: (a) not public; and (b) accessible to the individual subject of that data.

Subd. 3. Confidential data on individuals

"Confidential data on individuals" means data which is made not public by statute or federal law applicable to the data and is inaccessible to the individual subject of that data.

Subd. 9. Nonpublic data

"Nonpublic data" means data not on individuals that is made by statute or federal law applicable to the data: (a) not accessible to the public; and (b) accessible to the subject, if any, of the data.

Subd. 8a. Not public data

"Not public data" means any government data which is classified by statute, federal law, or temporary classification as confidential, private, nonpublic, or protected nonpublic.

Subd. 19. Summary data

"Summary data" means statistical records and reports derived from data on individuals but in which individuals are not identified and from which neither their identities nor any other characteristic that could uniquely identify an individual is ascertainable.

Subd. 8. Individual

"Individual" means a natural person. In the case of a minor or an individual adjudged mentally incompetent, "individual" includes a parent or guardian or an individual acting as a parent or guardian in the absence of a parent or guardian, except that the responsible authority shall withhold data from parents or guardians, or individuals acting as parents or guardians in the absence of parents or guardians, upon request by the minor if the responsible authority determines that withholding the data would be in the best interest of the minor.

Subd. 13. Protected nonpublic data

"Protected nonpublic data" means data not on individuals which is made by statute or federal law applicable to the data (a) not public and (b) not accessible to the subject of the data.

13.03 Access to government data

Subd. 1. Public data

All government data collected, created, received, maintained or disseminated by a state agency, political subdivision, or statewide system *shall be public unless classified* by statute, or temporary classification … or federal law … *as private or confidential*. [emphasis added]

Subd. 3. Request for access to data

(a) *Upon request … a person shall be permitted to inspect and copy public government data* …[emphasis added]

…

(f) If the responsible authority or designee determines that the requested data is classified so as to deny the requesting person access, the responsible authority or designee shall inform the requesting person of the determination either orally at the time of the request, or in writing as soon after that time as possible, and shall cite the specific statutory section, temporary classification, or specific provision of federal law on which the determination is based. …"

13.3805 Public health data

Subd. 1. Health data generally

(a) Definitions. As used in this subdivision:

(1) "Commissioner" means the commissioner of health.

(2) "Health data" means data on individuals created, collected, received, or maintained by the department of health, political subdivisions, or statewide systems relating to the identification, description, prevention, and control of disease or as part of an epidemiologic investigation the commissioner designates as necessary to analyze, describe, or protect the public health.

(b) Data on individuals.

(1) Health data are *private data* on individuals. [emphasis added] Notwithstanding section 13.05, subd. 9, health data may not be disclosed except as provided in this subd. and section 13.04.

(2) The commissioner or a local board of health as defined in section 145A.02, subd. 2, may disclose health data to the data subject's physician as necessary to locate or identify a case, carrier, or suspect case, to establish a diagnosis, to provide treatment, to identify persons at risk of illness, or to conduct an epidemiologic investigation.

(3) With the approval of the commissioner, health data may be disclosed to the extent necessary to assist the commissioner to locate or identify a case, carrier, or suspect case, to alert persons who may be threatened by illness as evidenced by epidemiologic data, to control or prevent the spread of serious disease, or to diminish an imminent threat to the public health. …"

144.053 Research studies confidential

Subd. 1. Status of data collected by commissioner

All information, records of interviews, written reports, statements, notes, memoranda, or other data procured by the state commissioner of health, in connection with studies conducted by the state commissioner of health, or carried on by the said commissioner jointly with other persons, agencies or organizations, or procured by such other persons, agencies or organizations, for the purpose of reducing the morbidity or mortality from any cause or condition of health shall be confidential and shall be used solely for the purposes of medical or scientific research.

144.335 Access to health records

Subd. 3a. Patient consent to release of records; liability

(a) A provider, or a person who receives health records from a provider, may not release a patient's health records to a person without a signed and dated consent from the patient or the patient's legally authorized representative authorizing the release, *unless the release is specifically authorized by law*. [emphasis added]

…

(d) Notwithstanding paragraph (a), health records may be released to an external researcher solely for purposes of medical or scientific research only as follows:

(1) health records generated before January 1, 1997, may be released if the patient has not objected or does not elect to object after that date;

(2) for health records generated on or after January 1, 1997, the provider must:

(i) disclose in writing to patients currently being treated by the provider that health records, regardless of when generated, may be released and that the patient may object, in which case the records will not be released; and

(ii) use reasonable efforts to obtain the patient's written general authorization that describes the release of records in item (i), which does not expire but may be revoked or limited in writing at any time by the patient or the patient's authorized representative;

(3) authorization may be established if an authorization is mailed at least two times to the patient's last known address with a postage prepaid return envelope and a conspicuous notice that the patient's medical records may be released if the patient does not object, and at least 60 days have expired since the second notice was sent; and the provider must advise the patient of the rights specified in clause (4); and

(4) the provider must, at the request of the patient, provide information on how the patient may contact an external researcher to whom the health record was released and the date it was released.

In making a release for research purposes the provider shall make a reasonable effort to determine that:

(i) the use or disclosure does not violate any limitations under which the record was collected;

(ii) the use or disclosure in individually identifiable form is necessary to accomplish the research or statistical purpose for which the use or disclosure is to be made;

(iii) the recipient has established and maintains adequate safeguards to protect the records from unauthorized disclosure, including a procedure for removal or destruction of information that identifies the patient; and

(iv) further use or release of the records in individually identifiable form to a person other than the patient without the patient's consent is prohibited.

Subd. 3b. Release of records to commissioner of health or health data institute

Subd. 3a does not apply to the release of health records to the commissioner of health or the health data institute *under chapter 62J*, provided that the commissioner encrypts the patient identifier upon receipt of the data." [emphasis added]

13.3806 Public health data coded elsewhere

Subd. 1. Scope

The sections referred to in subdivisions 2 to 20 are codified outside this chapter. Those sections classify data on public health as other than public, place restrictions on access to government data, or involve data sharing.

Subd. 2. Certain epidemiologic studies

Use of data collected by the commissioner of health under sections 176.234, 268.19, and 270B.14, subd. 11, is governed by section 144.0525.

Subd. 3. Public health studies

Data held by the commissioner of health in connection with public health studies are classified under section 144.053.

Subd. 4. Vital statistics

(a) Parents' social security number; birth record. Parents' social security numbers provided for a child's birth record are classified under section 144.215, subd. 4. …

(b) Foundling registration. The report of the finding of an infant of unknown parentage is classified under section 144.216, subd. 2.

(c) New record of birth. In circumstances in which a new record of birth may be issued under section 144.218, the original record of birth is classified as provided in that section.

(d) Vital records. Physical access to vital records is governed by section 144.225, subd. 1.

(e) Birth record of child of unmarried parents. Access to the birth record of a child whose parents were not married to each other when the child was conceived or born is governed by sections 144.225, subdivisions 2 and 4, and 257.73.

(f) Health data for birth registration. Health data collected for birth registration or fetal death reporting are classified under section 144.225, subd. 2a.

(g) Group purchaser identity for birth registration. Classification of and access to the identity of a group purchaser collected in association with birth registration is governed by section 144.225, subd. 6.

Subd. 5. School health records

(a) Student health data. Data collected for the health record of a school child are governed by section 144.29.

(b) Tuberculosis screening. Access to health records of persons enrolled in or employed by a school or school district for tuberculosis screening purposes is governed by section 144.441, subd. 8.

Subd. 6. Health records

Access to health records is governed by section 144.335.

Subd. 7. Immunization data

Sharing of immunization data is governed by section 144.3351.

Subd. 8. Hepatitis B maternal carrier

Sharing of information regarding the hepatitis B infection status of a newborn's mother is governed by section 144.3352.

Subd. 9. Human leukocyte antigen type registry

Data identifying a person and the person's human leukocyte antigen type which is maintained by a government entity are classified under section 144.336, subd. 1. …

Subd. 10. Health threat procedures

Data in a health directive issued by the commissioner of health or a board of health are classified in section 144.4186.

Subd. 11. Tuberculosis health threat

Data collected by the commissioner of health in connection with a tuberculosis health threat are classified under section 144.4813.

Subd. 12. Epidemiologic data

Epidemiologic data that identify individuals are classified under section 144.6581.

Subd. 13. Traumatic injury

Data on individuals with a brain or spinal injury collected by the commissioner of health are classified under section 144.665.

Subd. 14. Cancer surveillance system

Data on individuals collected by the cancer surveillance system are classified pursuant to section 144.69.

Subd. 15. Bloodborne pathogens

Data sharing between the emergency medical services agency and facilities is governed by section 144.7402, subd. 3.

Subd. 16. Test information

Information concerning test results is governed by section 144.7411.

Subd. 17. Lead exposure

Data on individuals exposed to lead in their residences are classified under sections 144.9502, subd. 9, and 144.9504, subd. 2.

Subd. 18. Terminated pregnancies

Disclosure of reports of terminated pregnancies made to the commissioner of health is governed by section 145.413, subd. 1. …

Subd. 19a. Maternal death

Access to and classification of medical data and health records related to maternal death studies are governed by section 145.901.

Subd. 20. Hazardous substance exposure

Disclosure of data related to hazardous substance exposure is governed by section 145.94.

Relevant HIPAA provisions

§ 164.512 Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required.

(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;

…

(iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation; or

…

(i) Standard: uses and disclosures for research purposes.

(1) Permitted uses and disclosures. A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that:

(i) Board approval of a waiver of authorization. The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by §164.508 for use or disclosure of protected health information has been approved by either:

(A) An Institutional Review Board (IRB), established in accordance with 7 CFR 1c.107, 10 CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 24 CFR 60.107, 28 CFR 46.107, 32 CFR 219.107, 34 CFR 97.107, 38 CFR 16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107, or 49 CFR 11.107; or

(B) A privacy board …

(ii) Reviews preparatory to research. The covered entity obtains from the researcher representations that:

(A) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;

(B) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and

(C) The protected health information for which use or access is sought is necessary for the research purposes.

(iii) Research on decedent's information. The covered entity obtains from the researcher:

(A) Representation that the use or disclosure is sought is solely for research on the protected health information of decedents;

(B) Documentation, at the request of the covered entity, of the death of such individuals; and

(C) Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

(2) Documentation of waiver approval. For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, under paragraph (i)(1)(i) of this section, the documentation must include all of the following:

(i) Identification and date of action. A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;

(ii) Waiver criteria. A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

(A) The use or disclosure of protected health information involves no more than minimal risk to the individuals;

(B) The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;

(C) The research could not practicably be conducted without the alteration or waiver;

(D) The research could not practicably be conducted without access to and use of the protected health information;

(E) The privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;

(F) There is an adequate plan to protect the identifiers from improper use and disclosure;

(G) There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and

(H) There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.

(iii) Protected health information needed. A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or privacy board has determined, pursuant to paragraph (i)(2)(ii)(D) of this section;

(iv) Review and approval procedures. A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures, as follows:

(A) An IRB must follow the requirements of the Common Rule, including the normal

review procedures (7 CFR 1c.108(b), 10 CFR 745.108(b), 14 CFR 1230.108(b), 15 CFR 27.108(b), 16 CFR 1028.108(b), 21 CFR 56.108(b), 22 CFR 225.108(b), 24 CFR 60.108(b), 28 CFR 46.108(b), 32 CFR 219.108(b), 34 CFR 97.108(b), 38 CFR 16.108(b), 40 CFR 26.108(b), 45 CFR 46.108(b), 45 CFR 690.108(b), or 49 CFR 11.108(b)) or the expedited review procedures (7 CFR 1c.110, 10 CFR 745.110, 14 CFR 1230.110, 15 CFR 27.110, 16 CFR 1028.110, 21 CFR 56.110, 22 CFR 225.110, 24 CFR 60.110, 28 CFR 46.110, 32 CFR 219.110, 34 CFR 97.110, 38 CFR 16.110, 40 CFR 26.110, 45 CFR 46.110, 45 CFR 690.110, or 49 CFR 11.110);

…

(v) Required signature. The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable.

Example for data practices within the IRB application

This is an example of a "Confidentiality and Privacy of Data" paragraph in the IRB application that covered:

- data classification under Minnesota Law;
- records retention; and
- specific security measures.

"… [P]ermission and release of information form … that will be signed by the parent/guardian of all study participants prior to turning in the questionnaire [is included]. … Specific results will be stored in the Minnesota Blood lead Surveillance database with a unique identifier for easy retrieval and analysis. Once the hard copy is entered into the database, they are stored in a locked cabinet when not under the physical control of an authorized employee. Record retention is consistent with the Record Retention Schedule for the EH unit [that is attached]. … Hard copy results are stored and retained for a period of 1 to 2 years … Electronic data is backed up nightly/weekly and then copied onto an electric storage medium for duplication and permanent retention. Electronic records are "double locked" using a password for system access and a second password for file access. Access is restricted to those employees with a "need to know." Blood lead test results are classified as private data by Minnesota statute (MS 144.9502)."

The Tennessen Warning

MINN. STAT. § 13.04, SUBD. 2

When the notice must be given

1. An individual
2. Is asked to supply
3. Private or confidential data
4. Concerning self.

All four conditions must be present to trigger the notice requirement.

When the notice does not need to be given

- The data subject is not an individual
- The subject offers information that has not been requested by the entity
- The information requested from the subject is about someone else
- The entity requests or receives information about the subject from someone else, or
- The information requested from the subject is public data about that subject.

Statements must be included that inform the individual

- Why the data are being collected from the individual and how the entity intends to use the data;
- Whether the individual may refuse or is legally required to supply the data;
- Any consequences to the individual of either supplying or refusing to supply the data; and
- The identity of other persons or entities authorized by law to receive the data.

Consequences of giving the notice

Private or confidential data on individuals may be collected, stored, used and released as described in the notice without liability to the entity.

Consequences of giving an incomplete notice, or not giving the notice at all

- Private or confidential data on individuals cannot be collected, stored, used or released for any purposes other than those stated in the notice unless:
- The individual subject of the data gives informed consent;
- The Commissioner of Administration gives approval; or
- A state or federal law subsequently authorizes or requires the new use or release.