

*PHI Subcommittee DRAFT LANGUAGE - new language in **bold**:*

INFORMATION COMING IN: MHDO will need to look at changing the confidentiality provisions of Title 22, Chapter 401, Section 1711-C.

Title 22, Section 1711-C, CONFIDENTIALITY OF HEALTH CARE INFORMATION:

1. Definitions ...

E. "Health care information" means information that directly identifies the individual and that relates to an individual's physical, mental or behavioral conditions, personal or family medical history or medical treatment or the health care provided to that individual. "Health care information" does not include information ~~that protects that anonymity of the individual by means of encryption or encoding of individual identifiers or information~~ pertaining to or derived from federally authorized or regulated research governed by ...Code of Federal Regulations... To the extent that such information is used in a manner that protects the identification of the individual. The Board of Directors of the Maine Health Data Organization shall adopt rules to define health care information that directly identifies an individual. Rules adopted pursuant to this paragraph are routine technical rules..."

Section 1711-C, CONFIDENTIALITY OF HEALTH CARE INFORMATION

6. Disclosure without authorization to disclose. A health care practitioner or facility may disclose, or when required by law must disclose, health care information without authorization to disclose under the circumstances stated in this subsection or as provided in subsection 11. Disclosure may be made without authorization as follows: ...

F. To the Maine Health Data Organization as required by and for use in accordance with Chapter 1683.

Title 22, Chapter 1683: MAINE HEALTH DATA ORGANIZATION

Section 8702 DEFINITIONS:

8702(4-B)Individually identifiable health information is information including demographic information about an individual reported to MHDO that relates to the past , present, or future physical or mental health or condition of an individual: the provision of health care to an individual: or the past, present or future payment for the provision of health care to an individual and that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual. For the purposes of this chapter it is synonymous with protected health information (PHI).

INFORMATION GOING OUT.

Section 8705-A ENFORCEMENT

(2) Rulemaking. The board shall adopt rules to implement this section. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A. The rules may contain procedures for monitoring compliance with this chapter. Rules adopted pursuant to this subsection must include a schedule of fines for: ...

C. Intentionally or knowingly and without authorization linking, using or disseminating individually identifiable health information on patients.

D. Intentionally or knowingly and without authorization linking, using, or disseminating information that identifies, or with respect to which there is a reasonable basis to believe the information can be used to identify health care practitioners performing abortions as defined in section 1596.

Section 8707. **GENERAL PUBLIC ACCESS TO DATA AND RULES**

- A. All data collected by MHDO that contain personally identifying health information are confidential. MHDO data may only be collected, stored and released according to this chapter and the rules enacted pursuant to it. MHDO data containing personally identifying health information may not be open to public inspection, are not public records for purposes of any state or federal freedom of access laws, and may not be examined in any judicial, executive, legislative, administrative, or other proceeding as to the existence or content of any individual's identifying health information. Decisions of the MHDO or persons and subcommittees thereof on data release are not reviewable.**
- B. General Public access; confidentiality.** The board shall adopt rules making available to any person, upon request, information, except privileged **individually identifiable** medical information and confidential information, provided to the organization under this chapter as long as individual patients are not directly or indirectly identified through a re-identification process.
- C. Rules. MHDO shall promulgate rules for the release of data governing all levels of information – de-identified data, limited data sets, and other individually identifiable health information. All uses shall be governed by principles of release of data and PHI to only that which is necessary for the stated purpose, governance by Data Use Agreements that provide adequate privacy and security measures; provisions for follow-up to make sure data is used as specified and that no personal health information is publically revealed, including rules for data suppression, MHDO board approval of release of more PHI than a limited data set as defined in HIPAA; and review of studies done to ensure personal health information is adequately protected.**

1. The board shall adopt rules to protect the identity of certain health care practitioners, as it determines appropriate, except that the identity of practitioners performing abortions as defined in section 1596 must be designated as confidential and must be protected. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter II-A.
2. Notice and comment period. The rules must establish criteria for determining whether information is confidential clinical data, confidential financial data or ~~privileged medical~~ **individually identifiable health** information and adopt procedures to give affected health care providers and payers notice and opportunity to comment in response to requests for information that may be considered confidential or privileged.
3. **Individual patients may only be directly or indirectly identified, including through a linking or re-identification process, as provided in this chapter and the rules. Any individually identifiable health information shall be used only for the purposes for which the MHDO releases it.**
5. Those persons gaining access to medical information about an [**individually**] identified patient use that information to the minimum extent necessary to accomplish the purposes of the research for which approval was granted and [**for no other purpose**].
6. The board may not grant approval ~~under this subsection~~ **for release of data** if the board finds that the proposed identification of or contact with patients would violate any state or federal law or diminish the confidentiality of health care information or the public's confidence in the protection of that information in a manner that outweighs the expected benefit to the public of the proposed investigation.
7. Rules for release, publication and use of data. The rules must govern the release, publication and use of analyses, reports or compilations derived from the health data made available by the organization. **The rules will apply to all data collected, stored, and released by MHDO including reports under Section 8712.**

D. Privacy and Security Protections required under Federal and State laws are complied with.

Section 8707-A PUBLIC HEALTH STUDIES

A. Permitted Uses and Disclosures. The MHDO is permitted to use and disclose protected health information (PHI), without an individual's authorization, to public health authorities for the following purposes:

(1) public health authorities, including the Maine CDC authorized by law to collect or receive such information for preventing or controlling disease, injury, or disability and to public health or other government authorities authorized to receive reports of child abuse and neglect;

(2) entities subject to FDA regulation regarding FDA regulated products or activities for purposes such as adverse event reporting, tracking of products, product recalls, and post-marketing surveillance;

(3) individuals who may have contracted or been exposed to a communicable disease when notification is authorized by law; and

(4) employers, regarding employees, when requested by employers, for information concerning a work-related illness or injury or workplace related medical surveillance, because such information is needed by the employer to comply with occupational health and safety statutes.

B. The state and federal public health authorities may use personal or protected health information for public health activities and is are permitted to disclose such information for public health activities as allowed by state and federal law, and in accordance with MHDO rules on data release.

Section 8707-B RESEARCH.

A. For research involving subjects with whom the researcher has no treatment or payer relationship, the MHDO may disclose protected health information for research purposes, without an individual's authorization, provided the researcher:

(1) obtains approved by an Institutional Review Board in compliance with federal law; or

(2) affirms that the use or disclosure sought is solely for research on the protected health information of decedents, that the protected health information sought is necessary for the research, and, at the request of the covered entity, documentation of the death of the individuals about whom information is sought;

(3) assures that the use or disclosure of PHI is only to prepare a research protocol or similar preparation for research, that the PHI is necessary for the research, and

(4) assures that individual patients may only be directly or indirectly identified, including through a linking or re-identification process, for the purposes of the study and the identification or linkage of individuals is destroyed after it is no longer need for the study; and

B. For research involving subjects with whom the researcher does have a treatment or payer relationship, or is engaging in research as a business associate of a treatment provider or payer, the MHDO may disclose protected health information for research purposes provided those persons conducting the research or investigation do not disclose medical information about any patient **[individually]** identified to any person not directly involved in the research without that patient's consent.

C. Those persons gaining access to medical information about an **[individually]** identified patient use that information to the minimum extent necessary to accomplish the purposes of the research for which approval was granted and **[for no other purpose];**

D. The protocol for any research is designed to preserve the confidentiality of all health care information that can be associated with identified patients, to specify the manner in which contact is made with patients and to maintain public confidence in the protection of confidential information.

E. The board may not grant approval under this subsection if the board finds that the proposed identification of or contact with patients would violate any state or federal law or diminish the confidentiality of health care information or the public's confidence in the protection of that information in a manner that outweighs the expected benefit to the public of the proposed investigation.

F. There is a data use agreement in effect with established protocols that have been approved by the board for safeguarding confidential or privileged information, **and for assuring there will be no disclosures of PHI which may reasonably be used to identify an individual.**

Section 8707-C. PAYER AND PROVIDER ACCESS TO PROTECTED HEALTH INFORMATION

1. Permitted Uses and Disclosures. The MHDO is permitted to use and disclose protected health information (PHI), without an individual's authorization, for the following purposes or situations:

A. Treatment, Payment, and Health Care Operations. The MHDO may disclose protected health information for the treatment activities of any health care provider, the payment activities of a covered entity and of any health care provider, or the health care operations of a covered entity involving either quality or competency assurance activities or fraud and abuse detection and compliance activities, if the covered entities have or had a relationship with the individual and the protected health information pertains to the relationship.

i. Treatment is the provision, coordination, or management of health care and related services for an individual by one or more health care providers, including consultation between providers regarding a patient and referral of a patient by one provider to another.

ii. Payment encompasses activities of a health plan to obtain premiums, determine or fulfill responsibilities for coverage and provision of benefits, and furnish or obtain reimbursement for health care delivered to an individual and activities of a health care provider to obtain payment or be reimbursed for the provision of health care to an individual.

iii. Health care operations are any of the following activities: (a) quality assessment and improvement activities, including case management and care coordination; (b) competency assurance activities, including provider or health plan performance evaluation, credentialing, and accreditation; (c) conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs; (d) specified insurance functions, such as underwriting, risk rating, and reinsuring risk; (e) business planning, development, management, and administration; and (f) business management and general administrative activities of the entity, including but not limited to: de-identifying protected health information, creating a limited data set, and certain fundraising for the benefit of the covered entity.

2. Minimum Necessary. The MHDO will develop policies and procedures that reasonably limit its disclosures of, and requests for, protected health information for payment and health care operations to the minimum necessary.

3. For MHDO to release PHI under this section MHDO will provide an individual protection mechanism by which an individual may opt out from participation to prohibit the MHDO from disclosing the individuals health care information under this section. This opt out should be coordinated with the statewide health information exchange to the extent this can reasonably be done. The opt-out mechanism shall meet the conditions of 22 MRS Section 1711-C (18)C-K to the extent applicable.

4. For MHDO to release PHI under this section that contains mental health and or HIV MHDO will provide an individual protection mechanism by which an individual must opt in allowing the MHDO to disclose the individuals health care information under this section. This opt in should be coordinated with the statewide health information exchange to the extent this can reasonably be done.

Summary of the PHI Subcommittee:

The overarching idea that informed the subcommittee's work was the idea that concepts regarding use and limits on use of protected (identified) health information have been extensively examined, refined, and specified in the HIPAA regulations. So in making suggestions for expanded use of PHI the subcommittee has tried whenever practicable to integrate limits and definitions from HIPAA or to exceed them. For example the opt-out provision of the draft language on treatment-payer-health operations level is greater protection than HIPAA requires. It is also equals the protections required of the state's identified health information exchange-HealthInfoNet. The subcommittee believes these ideas are becoming well understood in the regulated community and are therefore more meaningful and acceptable to providers, payers, and professionals. In addition HIPAA principles should inform information and interactions with the public/patients about expanded use of MHDO data.

MHDO should look at specifically defining protected health information. We have included a definition that comes from the language of HIPAA. This definition would be applicable both to information coming in and information going out from MHDO.

The statutory changes should be keyed to rules that limit use of protected health information to what is needed for the purpose at hand. Another issue is downstream protection of MHDO data. Some states require approval of the actual studies by their data organization or a subcommittee before release. Also, there are rules on suppression of data if numbers alone could be used to identify people due to the small numbers involved. For example Maine CDC uses cell size 5 for suppression.

The challenges of providing for expanded use of MHDO's All-Payer Claims Database, and other MHDO data are great. The Subcommittee believes, however, that the benefits to the Maine public from expanded use of MHDO data outweigh the challenges of coordinating that effort with HIPAA regulations, and adequate privacy protections for use of protected health information by MHDO.