RECOMMENDATIONS REGARDING APPROPRIATE ACCESS TO PROTECTED HEALTH INFORMATION

Report to the Maine Health Data Organization (MHDO) Board of Directors

From the MHDO Subcommittee on Appropriate Access to PHI

August 8, 2013

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I. Background

The MHDO Board of Director established the MHDO Subcommittee on Appropriate Access to PHI on March 6, 2013 (the "PHI Subcommittee") "to develop and provide recommendations, including suggested enabling legislation, to the MHDO Board at the Boards retreat in August 2013. Specifically, the Charge of the PHI Subcommittee is as follows:

1. Develop draft principles to guide the use of protected health information to improve the utility of MHDO data sets;

2. Propose a governance structure to oversee the release and use of protected health information that includes appropriate privacy and security safeguards;

3. Recommend amendments to Maine law and regulation to allow the appropriate use of protected health information

Protected Health Information (PHI) is any information about health status, provision of health care, or payment for health care that can be linked to a specific individual.

II. Advisory Committee Members

In March the MHDO Board appointed the members of the PHI Subcommittee representing a multi –stakeholder composition of providers, employers, consumers, health plans, and the public sector. The members of the Subcommittee are:

- David Winslow,(Co-Chair)
  Maine Hospital Association

- Michael Dilorenzo, (Co-Chair)
  Maine Health Management Coalition

- Jim Leonard
  Department of Health and Human Services

- Andy Ellis
  Anthem Blue Cross and Blue Shield of Maine

- Poppy Arford
  Consumer

Staff to the Subcommittee:

Karynlee Harrington
Maine Health Data Organization

Deanna White, Esq.
Assistant Attorney General

Dawn Gallagher
Office for Health Information Technology

III. Issues Considered by the PHI Subcommittee

The PHI Subcommittee was briefed on the key elements of the Federal Privacy Rule including who is covered, what information is protected and how protected health information can be used and disclosed.

The information provided to the PHI Subcommittee is summarized below and came from the U.S. Department of Health and Human Services website at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html

Overview

- The U.S. Department of Health and Human Services ("HHS") issued the Privacy Rule to implement the requirement of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

- The Privacy Rule (The *Standards for Privacy of Individually Identifiable Health Information)* are a set of national standards for the protection of certain health information.

- The Privacy Rule standards address the **use and disclosure of individuals' health information**—called "**protected health information**" by **organizations subject to the Privacy Rule** — called **"covered entities**," as well as standards for individuals' privacy rights to understand and control how their health information is used.

- A major goal of the Privacy Rule is to assure that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health and well being.

- **The Privacy Rule applies to "covered entities"** defined as health plans, health care clearinghouses, and to any health care provider who transmits health information in electronic form in connection with transactions for which the Secretary of HHS has adopted standards under HIPAA.

What Information is Protected

- The Privacy Rule protects all PHI- *"individually identifiable health information"* held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral.

- HIPAA identifies 18 elements (including name, telephone number, address, birth date, email address, social security number, and unique identifying number such as a medical record number) that are considered as elements of PHI

- There are no restrictions on the use or disclosure of de-identified health information. De-identified health information neither identifies nor provides a reasonable basis to identify an individual.

General Principle for Uses and Disclosures of PHI

- A major purpose of the Privacy Rule is to define and limit the circumstances in which an individual's protected heath information may be used or disclosed by covered entities.

- A covered entity may not use or disclose protected health information, except either: (1) as the Privacy Rule permits or requires; or (2) as the individual who is the subject of the information (or the individual's personal representative) authorizes in writing.

Permitted Uses and Disclosures of PHI

- A covered entity is permitted, but not required, to use and disclose protected health information, without an individual's authorization, for the following purposes or situations:
    - To the Individual (unless required for access or accounting of disclosures);
    - Treatment, Payment, and Health Care Operations;
    - Opportunity to Agree or Object;
    - Incident to an otherwise permitted use and disclosure;
    - Public Interest and Benefit Activities;
    - Limited Data Set for the purposes of research, public health or health care operations.

- **Treatment, Payment, Health Care Operations.** A covered entity may use and disclose protected health information for its own treatment, payment, and health care operations activities. A covered entity also may disclose protected health information for the treatment activities of any health care provider, the payment activities of another covered entity and of any health care provider, or

the health care operations of another covered entity involving either quality or competency assurance activities or fraud and abuse detection and compliance activities, if both covered entities have or had a relationship with the individual and the protected health information pertains to the relationship.

- The Privacy Rule permits use and disclosure of protected health information, without an individual's authorization or permission, for 12 national priority purposes.

    - **Research**: The Privacy Rule permits a covered entity to use and disclose protected health information for research purposes, **without** an individual's authorization, provided the covered entity obtains either: (1) documentation that an alteration or waiver of individuals' authorization for the use or disclosure of protected health information about them for research purposes has been approved by an Institutional Review Board or Privacy Board; (2) representations from the researcher that the use or disclosure of the protected health information is solely to prepare a research protocol or for similar purpose preparatory to research, that the researcher will not remove any protected health information from the covered entity, and that protected health information for which access is sought is necessary for the research; or (3) representations from the researcher 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.

    - A covered entity also may use or disclose, without an individuals' authorization, a limited data set of protected health information for research purposes.

    - ***Public Health Activities.*** Covered entities may disclose protected health information to: (1) public health authorities 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 the Occupational Safety and Health Administration (OHSA), the Mine Safety and Health Administration (MHSA), or similar state law.

The PHI Subcommittee was briefed on the key elements of MHDO's governing Statute Title 22, Chapter 1683 and other Maine State Laws regarding confidentiality and protected health information.

Deanna

Feedback from LD 1818 Survey and MHDO End Users

The LD 1818 Work Group issued an electronic survey in late spring to 140 groups and individuals. Four major themes emerged from the results of the survey. One of the themes was the following:

> *Balance Consumer Privacy considerations regarding the safeguarding and disclosure of Protected Health Information (PHI) with the societal imperative to drive higher quality and more affordable health care.*

The LD 1818 Work Group concluded that increasing access to personal health information for purposes other than what are currently thought of as "treatment, payment and operations of the practice" requires further policy discussions and that there could be legitimate and appropriate reasons, including public policy considerations, for increasing access to PHI.

Description of:

PCMH and Medicare providing PHI for MAPCP project

Study the VA is doing with an identified set of VA data

Feedback from practices that want PHI

IV. Subcommittee Recommendations

In order to meet the Organizations objective as defined in 22 §8703. 1.

The purposes of the organization are to create and maintain a useful, objective, reliable and comprehensive health information database that is used to improve the health of Maine citizens and to issue reports, as provided in section 8712. This database must be publicly accessible while protecting patient confidentiality and respecting providers of care. The organization shall collect, process, analyze and report clinical, financial, quality and restructuring data as defined in this chapter.

The PHI Subcommittee is recommending the following changes:

1. Allow for the release of PHI in the following circumstances:

    - Research-construct rules that follow the requirement under HIPAA
    - To providers with the patient consent –follow existing law/rule