

MaineHealth

December 14, 2015

VIA ELECTRONIC SUBMISSION AT: Debra.J.Dodge@Maine.gov

RE: Proposed Rule Number 2015-P206 (MHDO Chapter 120)

Ms. Debra J. Dodge
Maine Health Data Organization
151 Capitol Street
102 State House Station
Augusta, ME 04333

Dear Ms. Dodge:

MaineHealth appreciates the opportunity to submit the following comments on the recently proposed Maine Health Data Organization (MHDO) Data Release Rule which repeals and replaces existing MHDO Rule Chapter 120 concerning *Release of Data to the Public*. We understand the MHDO's stated goal to collect and release Protected Health Information (PHI) in very specific circumstances to advance health care delivery system and payment reform initiatives.

MaineHealth and our member health organizations have invested a great deal of resources into our own clinical information systems and continually work with payers to align claims information with our own clinical information so we can best care for the populations we serve.

As a covered entity under the Health Insurance Portability and Accountability Act (HIPAA) and direct provider of patient care, MaineHealth sees value in the ability to access Level III data for the purpose of improving patient care. The U.S. Department of Health and Human Services (DHHS) defines a covered entity as, "(1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards. Generally, these transactions concern billing and payment for services or insurance coverage. For example, hospitals, academic medical centers, physicians, and other health care providers who electronically transmit claims transaction information directly or through an intermediary to a health plan are covered entities. Covered entities can be institutions, organizations, or persons."¹

¹ National Institutes of Health. Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule. (DHHS Publication No. 03-5388).

Researchers are considered covered entities if they are also health care providers who electronically transmit health information in connection with any transaction for which DHHS has adopted a standard. For example, physicians who conduct clinical studies or administer experimental therapeutics to participants during the course of a study must comply with the Privacy Rule if they meet the HIPAA definition of a covered entity.

As an organizing framework, MaineHealth is generally supportive of Level III data being made available by the MHDO to Covered Entities as defined in the regulation and subject to HIPAA requirements related to the protection of the privacy and security of health information, permitted uses and disclosures, and limiting uses and disclosures to the minimum necessary. MaineHealth, however, strongly opposes the release of Social Security numbers under any circumstances.

MaineHealth is also supportive of Covered Entities engaging Business Associates to assist with health improvement efforts. The release of Level III data should, however, be restricted to Covered Entities and their Business Associates and subject to detailed Data Use Agreements with the MHDO. The [U.S. Department of Health and Human Services](#) states, “If a covered entity engages a **business associate** to help it carry out its health care activities and functions, the covered entity must have a written business associate contract or other arrangement with the business associate that establishes specifically what the business associate has been engaged to do and requires the business associate to comply with the Rules’ requirements to protect the privacy and security of protected health information. In addition to these contractual obligations, business associates are directly liable for compliance with certain provisions of the HIPAA Rules.”²

MaineHealth acknowledges the consideration the proposed rule has given to the commercialization or sale of re-packaged MHDO data. However, we would like clarification of the following underlined statement, “A data recipient may not sell, re-package or in any way make MHDO Data available at the individual element level, unless the ultimate viewers of that data have applied to MHDO for this data, been approved for such access and signed an MHDO DUA. Authorized Redistributors of the MHDO Data can use the MHDO Data for inclusion in a larger composite database or to produce reports that are publically released.” MaineHealth strongly opposes the release of PHI for any purposes other than improvement of patient care. The sharing of patient identifiable data for commercial purposes, absent patient consent, is not authorized by HIPAA and conflicts with the federal policy safeguarding patient confidentiality embodied by HIPAA. In no way should such uses be contemplated by the MHDO.

² U.S. Department of Health and Human Services. (n.d.). For Covered Entities and Business Associates. Retrieved from <http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/index.html>

In addition, given the complexity associated with the proposed Maine Health Data Organization (MHDO) Data Release Rule, MaineHealth believes a more robust oversight and governance process needs to be instituted. The MHDO's process of approving requests for claims data with identifiable patient information should require unanimous approval from the committee charged with reviewing data release requests, and with such approval to be given if -- and only if -- the permitted uses have been properly established and assurances that safeguards will be executed to prevent prohibited or unauthorized uses.

Finally, we appreciate the agency responses to our December 29, 2014 comments concerning the Chapter 120 draft rule. We want to reiterate those concerns related to the release of individually identifiable practitioner data elements and stress the importance of the MHDO ensuring the accuracy and reliability of such data.

Thank you for this opportunity to comment on the proposed Chapter 120 regulations. Of paramount concern to us is the establishment of strict criteria and safeguards for the request, release and use of Protected Health Information while still allowing Level III data to flow between clinicians and their patients which can improve individual outcomes. Please do not hesitate to contact me directly at (207) 661-7001 or CMcHugh@mainehealth.org for clarification or additional questions.

Sincerely,

Colin McHugh
Senior Vice President, Network Developing & Contracting
MaineHealth