

Annual List of Rule-Making Activity
Rules Adopted January 1, 2016 to December 31, 2016
Prepared by the Secretary of State, pursuant to 5 MRS, §8053-A, sub-§5

Agency name: **Maine Health Data Organization**
Umbrella-Unit: **94-270**
Statutory authority: 22 MRS §§ 8704 sub-§4, §8708; 24-A MRS §6951(2),(3);
Resolve 2015 ch. 71
Chapter number/title: **Ch. 270**, Uniform Reporting System for Quality Data Sets
Filing number: **2016-072**
Effective date: 6/1/2016
Type of rule: Major Substantive
Emergency rule: No

Principal reason or purpose for rule:

These changes eliminate duplicative reporting by Maine hospitals to both a state and national source; improve access to Healthcare Associated Infection (HAI) outcome measures and all other Centers for Medicare & Medicaid Services (CMS) mandated reporting requirements to National Healthcare Safety Network (NHSN); and update/clarify provisions in the rule as needed.

Basis statement / summary:

The Maine Health Data Organization is authorized by statute to collect quality data from hospitals and ambulatory surgery facilities to support the set of quality measures adopted by the Maine Quality Forum with the goal to improving the quality of healthcare in Maine.

This major substantive rule was provisionally adopted by the Maine Health Data Organization on January 7, 2016. As a major substantive rule, it was sent to the Legislature for approval. On March 29, 2016, the Legislature authorized adoption of the amended rule, as an emergency. Resolves 2015 ch. 71.

Fiscal impact of rule:

There is no fiscal impact on state municipalities, counties or businesses.

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Agency name: **Maine Health Data Organization**
Umbrella-Unit: **94-270**
Statutory authority: PL 2013 ch. 528; 22 MRS §8704(4); Resolves 2015 ch. 79;
22 MRS ch. 1683
Chapter number/title: **Ch. 120**, Release of Data to the Public
Filing number: **2016-108**
Effective date: 7/28/2016
Type of rule: Major Substantive
Emergency rule: No

Principal reason or purpose for rule:

This change repeals and replaces MHDO's current data release rule Ch. 120 in order to implement the provisions of PL 2013 ch. 528, "An Act to Amend Laws Relating to Health Care Data".

This rule specifies the permissible uses of the MHDO data; defines the different levels of data file types Level I, II, and Level III; the process for which data requests will be reviewed by MHDO; the data release process; public notice of data requests and opportunity for public comments; the appeal rights for data providers; the MHDO Data use Agreement (MHDO DUA); MHDO internal use of the data; and the security and protection of the MHDO Data. Many of these changes align with the concepts of the *Health Insurance Portability and Accountability Act* (HIPAA). Specifically, these changes allow for the following:

- data user's to request and receive direct patient identifier's when that is necessary for the data user's study and they meet numerous requirements protecting that information;
- provides a method for subjects of data to "opt-out" of Level III (Health data with Direct Patient Identifiers) data releases which simplifies the review and appeal process for data provider's claims of proprietary information;
- all data sets released by the MHDO, including the "de-identified" or Level I data set require a data use agreement (DUA), and approval by the Executive Director;
- provides for one Data Release Subcommittee of the MHDO Board of Directors; and,
- specifies data protections and practices such as "minimum necessary", MHDO's DUA and breach notification, and promulgates the MHDO's ability to levy large fines for misuse of MHDO data for financial or personal gain.

Copies of these proposed rules can be reviewed and printed from the MHDO website at <https://mhdo.maine.gov/rules.htm> or, to receive a paper copy call (207) 287-6722.

Basis statement / summary:

The Maine Health Data Organization is authorized by statute to collect health care data. This chapter governs the release of data submitted to the MHDO. The purpose of this rule is to specify the permissible uses of the data (Level I, II, and III); the process for which data requests will be reviewed and released; public notice of data requests; the MHDO Data Use Agreement, MHDO internal use of the data, and the security and protection of the MHDO Data.

This major substantive rule was provisionally adopted by the Maine Health Data Organization on March 3, 2016. As a major substantive rule, it was sent to the Legislature for approval. On April 16, 2016 the Legislature authorized adoption of the amended rule, as an emergency. Resolves 2015 ch.79.

This rule change repeals and replaces the current language found in the MHDO's data release rule in order to implement the provisions of PL 2013 ch. 528, "An Act to Amend Laws Relating to Health Care Data". This overhaul includes several major themes:

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- breaks down data sets into three different levels based on whether any elements of identifying information are involved; Level I data is De-Identified data; Level II is the MHDO's Limited Data Set and Level III data is our Direct Patient Identifiers;
- includes appendices listing the actual data elements in each data set, which improves public transparency about what the MHDO does;
- clarifies data users ability to request and receive direct patient identifier's when that is necessary for the data user's study and they meet the numerous requirements protecting that information;
- clarifies that all data sets released by MHDO, including the "de-identified" or Level I data set require a data use agreement, and approval by the Executive Director, as additional protections;
- provides a method for subjects of data to "opt-out" of a Level III data releases;
- clarifies that charge data at the individual level is confidential and is not released by MHDO except at an aggregate/average level;
- streamlines the review and appeal process for data provider's claims of proprietary information;
- specifies data protections and practices such as "minimum necessary," MHDO DUA's and breach notification, and Promulgates the MHDO's ability to levy large fines for misuse of MHDO benefit for financial or personal gain;
- aligns many existing MHDO practices with the concepts of the *Health Insurance Portability and Accountability Act (HIPAA)*; and
- establishes a Data Release Subcommittee of the MHDO Board of Directors for the review and decision of all Level III data requests.

Fiscal impact of rule:

There is no fiscal impact on state municipalities, counties or businesses.