**BASIS STATEMENT**

**90-590 Chapter 120: Release of Data to the Public**

**MAJOR SUBSTANTIVE**

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, Chapter 528, “An Act to Amend Laws Relating to Health Care Data”. This overhaul includes several major themes:

* breaks down data sets into three different levels based on whether any elements of identifying information are involved; Level 1 data is De-Identified data; Level 2 is the MHDO’s Limited Data Set and Level 3 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 3 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; and
* aligns many existing MHDO practices with the concepts of the Health Insurance Portability and Accountability Act (HIPAA);
* establishes a Data Release Subcommittee of the MHDO Board of Directors for the review and decision of all Level 3 data requests.

**STATUTORY AUTHORITY FOR THIS RULE**: PL 2013, Chapter 528, 22 M.R.S.A. §8704(4); and Resolves 2015, ch.79.

**EFFECTIVE DATE**: This rule will become effective 30 days after it is filed with the Secretary of State.