



126th MAINE LEGISLATURE

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Legislative Document

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H.P. 1246

House of Representatives, January 21, 2014

An Act To Amend Laws Relating to Health Care Data

Submitted by the Department of Professional and Financial Regulation pursuant to Joint Rule 204.

Reference to the Committee on Health and Human Services suggested and ordered printed.

Millicent M. MacFarland
MILLICENT M. MacFARLAND
Clerk

Presented by Representative MALABY of Hancock.
Cosponsored by Senator GRATWICK of Penobscot and
Representatives: GATTINE of Westbrook, KESCHL of Belgrade, PRINGLE of Windham.

1 **Be it enacted by the People of the State of Maine as follows:**

2 **Sec. 1. 22 MRSA §1711-C, sub-§1, ¶E**, as amended by PL 1999, c. 512, Pt. A,
3 §5 and affected by §7 and c. 790, Pt. A, §§58 and 60, is further amended to read:

4 E. "Health care information" means information that directly identifies ~~the~~, or with
5 respect to which there is a reasonable basis to believe the information could be used
6 to identify, an individual and that relates to an the individual's physical, mental or
7 behavioral condition, personal or family medical history or medical treatment or the
8 health care provided to that individual, including demographic information,
9 information related to payment for provision of health care and protected health
10 information as defined in 45 Code of Federal Regulations, Section 160.103 (2013).
11 "Health care information" does not include information ~~that protects the anonymity of~~
12 ~~the individual by means of encryption or encoding of individual identifiers or~~
13 ~~information~~ pertaining to or derived from federally sponsored, authorized or
14 regulated research governed by 21 Code of Federal Regulations, Parts 50 and 56 and
15 45 Code of Federal Regulations, Part 46, to the extent that such information is used in
16 a manner that protects the identification of individuals. The Board of Directors of the
17 Maine Health Data Organization shall adopt rules to define health care information
18 that directly identifies an individual. Rules adopted pursuant to this paragraph are
19 routine technical rules as defined in Title 5, chapter 375, subchapter ~~H-A~~ 2-A.

20 "Health care information" does not include information that is created or received by
21 a member of the clergy or other person using spiritual means alone for healing as
22 provided in Title 32, sections 2103 and 3270.

23 **Sec. 2. 22 MRSA §1711-C, sub-§6, ¶F-3** is enacted to read:

24 F-3. To the Maine Health Data Organization as required by and for use in
25 accordance with chapter 1683. Health care information, including protected health
26 information, as defined in 45 Code of Federal Regulations, Section 160.103 (2013),
27 submitted to and maintained by the Maine Health Data Organization must be
28 protected by means of encryption;

29 **Sec. 3. 22 MRSA §8702, sub-§1-B** is enacted to read:

30 **1-B. Business associate.** "Business associate" has the same meaning as under 45
31 Code of Federal Regulations, Section 160.103 (2013).

32 **Sec. 4. 22 MRSA §8702, sub-§2-A** is enacted to read:

33 **2-A. Covered entity.** "Covered entity" has the same meaning as under 45 Code of
34 Federal Regulations, Section 160.103 (2013).

35 **Sec. 5. 22 MRSA §8702, sub-§8-C** is enacted to read:

36 **8-C. Protected health information.** "Protected health information" has the same
37 meaning as under 45 Code of Federal Regulations, Section 160.103 (2013) and includes
38 individually identifiable health information such as demographic information about an
39 individual reported to the organization that relates to the past, present or future physical

1 or mental health or condition of the individual; the provision of health care to an
2 individual; or the past, present or future payment for the provision of health care to an
3 individual and that identifies, or with respect to which there is a reasonable basis to
4 believe the information could be used to identify, the individual.

5 **Sec. 6. 22 MRSA §8705-A, first ¶**, as enacted by PL 2003, c. 659, §2, is
6 amended to read:

7 The board shall adopt rules to ensure that payors and providers file data as required
8 by section 8704, subsection 1; that users that obtain health data and information from the
9 organization safeguard the identification of patients and health care practitioners as
10 required by section ~~8707~~ 8714, subsections ~~1 and 2~~, 3 and 4; and that payors and
11 providers pay all assessments as required by section 8706, subsection 2.

12 **Sec. 7. 22 MRSA §8705-A, sub-§3**, as amended by PL 2007, c. 136, §4, is
13 further amended to read:

14 **3. Fines.** The following provisions apply to enforcement actions under this section
15 except for circumstances beyond a person's or entity's control.

16 A. When a person or entity that is a health care facility or payor violates the
17 requirements of this chapter, except for section ~~8707~~ 8714, that person or entity
18 commits a civil violation for which a fine of not more than \$1,000 per day may be
19 adjudged. A fine imposed under this paragraph may not exceed \$25,000 for any one
20 occurrence.

21 B. A person or entity that receives data or information under the terms and
22 conditions of section ~~8707~~ 8714 and intentionally or knowingly uses, sells or
23 transfers the data in violation of the board's rules for commercial advantage,
24 pecuniary gain, personal gain or malicious harm commits a civil violation for which a
25 fine not to exceed \$500,000 may be adjudged.

26 C. A person or entity not covered by paragraph A or B that violates the
27 requirements of this chapter, except for section ~~8707~~ 8714, commits a civil violation
28 for which a fine of not more than \$100 per day may be adjudged. A fine imposed
29 under this paragraph may not exceed \$2,500 for any one occurrence.

30 **Sec. 8. 22 MRSA §8707**, as amended by PL 2011, c. 524, §4, is repealed.

31 **Sec. 9. 22 MRSA §§8714 to 8717** are enacted to read:

32 **§8714. General public access to data; rules**

33 The board shall adopt rules to provide for public access to data allowed under this
34 chapter and to implement the requirements of this section.

35 **1. Confidentiality.** All data collected by the organization that contain protected
36 health information are confidential. Data of the organization may be collected, stored and
37 released only in accordance with this chapter and rules adopted pursuant to this chapter.
38 Data of the organization containing protected health information may not be open to
39 public inspection, are not public records for purposes of any state or federal freedom of

1 access laws and may not be examined in any judicial, executive, legislative,
2 administrative or other proceeding as to the existence or content of any individual's
3 identifying health information. Decisions of the organization or employees and
4 subcommittees of the organization on data release are not reviewable.

5 **2. General public access; confidentiality.** The board shall adopt rules making
6 information provided to the organization under this chapter available to any person, upon
7 request, except protected health information and other confidential information, as long
8 as an individual is not identified either directly, or through a reidentification process, or
9 through release of information with respect to which there is a reasonable basis to believe
10 the information could be used to identify the individual. Rules adopted pursuant to this
11 subsection are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A.

12 **3. Release of data.** The board shall adopt rules for the release of data governing all
13 levels of information in the form of de-identified data, limited data sets and protected
14 health information. All uses of released data are governed by the following principles of
15 release:

16 A. Release of protected health information must be limited to only information that
17 is necessary for the stated purpose of the release;

18 B. Data releases must be governed by data use agreements that provide adequate
19 privacy and security measures;

20 C. Follow-up must be provided to ensure data are used as specified and that no
21 protected health information is publicly revealed. The board shall adopt rules
22 providing for any necessary data suppression; and

23 D. Release of more protected health information than a limited data set as described
24 in 45 Code of Federal Regulations, Section 164.514(e) must be approved by the
25 board.

26 **4. Certain practitioners.** The board shall adopt rules to protect the identity of
27 certain health care practitioners, as it determines appropriate, except that the identity of
28 practitioners performing abortions as defined in section 1596 must be designated as
29 confidential and may not be disclosed. Rules adopted pursuant to this subsection are
30 major substantive rules as defined in Title 5, chapter 375, subchapter 2-A.

31 **5. Notice and comment period.** The board shall adopt rules to establish criteria for
32 determining whether information is confidential clinical data, confidential financial data
33 or other protected health information and specify procedures to give affected health care
34 practitioners and payors notice and opportunity to comment in response to requests for
35 information that may be considered confidential.

36 **6. Identifying information.** The board shall adopt rules to provide that individuals
37 may be directly or indirectly identified, including through a linking or reidentification
38 process, only as provided in this chapter and the rules of the board. Any protected health
39 information may be used only for the purposes for which the organization releases it.

40 **7. Minimum use.** The board shall adopt rules to provide that persons gaining access
41 to protected health information may use that information to the minimum extent

1 necessary to accomplish the purposes for which approval was granted and for no other
2 purpose.

3 **8. Limitation on release.** The board may not grant approval for release of data if
4 the board finds that the proposed identification of or contact with individuals would
5 violate any state or federal law or diminish the confidentiality of health care information
6 or the public's confidence in the protection of that information in a manner that outweighs
7 the expected benefit to the public of the proposed investigation.

8 **9. Release; publication and use of data.** The board shall adopt rules to govern the
9 release, publication and use of analyses, reports and compilations derived from the health
10 data made available by the organization. The rules must apply to all data collected,
11 stored and released by the organization, including reports under section 8712.

12 **10. Other privacy protections.** The board shall adopt rules to ensure compliance
13 with all privacy and security protections required under federal and state laws.

14 **11. Choice regarding disclosure of information.** The board shall adopt rules to
15 address the provisions for requirements regarding the disclosure of information in section
16 8717, subsection 3.

17 **§8715. Public health**

18 **1. Permitted use and disclosure to public health authorities.** The organization
19 may disclose protected health information, without an individual's authorization, to a
20 public health authority for public health purposes mandated by state or federal law.

21 **2. Use by public health authority.** A state or federal public health authority to
22 which protected health information has been disclosed under subsection 1 may use that
23 information for public health activities and may disclose that information for public
24 health activities as allowed by state or federal law and in accordance with board rules on
25 data release adopted pursuant to section 8714.

26 **3. Data use agreement.** Prior to disclosing protected health information to a public
27 health authority under subsection 1, the organization shall enter into a data use agreement
28 with the public health authority. The agreement must have protocols that have been
29 approved by the board for safeguarding confidential information and for ensuring there
30 will be no disclosures of protected health information.

31 **§8716. Health care improvement studies**

32 The board may approve the disclosure of protected health information to persons
33 conducting health care improvement studies, subject to the following conditions.

34 **1. Disclosure to study entities.** For health care improvement studies, regarding
35 health care utilization, improvement, cost or quality and involving patients with whom
36 the study entity has a treatment or payer relationship, whether the study is funded by the
37 Federal Government or the State Government or private persons, the organization may
38 disclose protected health information to a study entity who is a covered entity or to the
39 covered entity's business associates if those persons conducting the study do not disclose

1 protected health information to any person not directly involved in the study without
2 consent from the subject of the protected health information.

3 **2. Recipients of information.** A person receiving protected health information
4 under subsection 1 may use that information only to the minimum extent necessary to
5 accomplish the purposes of the study for which approval was granted and for no other
6 purpose.

7 **3. Confidentiality; protocol.** The protocol for any study entity receiving protected
8 health information under subsection 1 must be designed to preserve the confidentiality of
9 all health care information that can be associated with identified patients, to specify the
10 manner in which contact is made with patients and to maintain public confidence in the
11 protection of confidential information.

12 **4. Additional protection.** The board may not grant approval to a study entity under
13 this section for the disclosure of protected health information if the board finds that the
14 proposed identification of or contact with patients would violate any state or federal law
15 or diminish the confidentiality of health care information or the public's confidence in the
16 protection of that information in a manner that outweighs the expected benefit to the
17 public of the proposed investigation.

18 **5. Data use agreement.** Prior to disclosing protected health information to a study
19 entity pursuant to subsection 1, the organization shall enter into a data use agreement with
20 the study entity. The agreement must have protocols that have been approved by the
21 board for safeguarding confidential information and for ensuring there will be no
22 disclosures of protected health information.

23 **§8717. Covered entities' access to protected health information**

24 **1. Permitted uses and disclosures; definitions.** The organization may disclose
25 protected health information without authorization by the subject of the information for
26 the treatment activities of any health care provider, the payment activities of a covered
27 entity and of any health care provider or the health care operations of a covered entity or
28 its business associates involving either quality or competency assurance activities or
29 fraud and abuse detection and compliance activities, if the covered entity has or had a
30 relationship with the subject of the information and the protected health information
31 pertains to the relationship. For the purposes of this section:

32 A. "Health care operations" means any of the following activities of a covered entity:

33 (1) Quality assessment and improvement activities, including case management
34 and care coordination;

35 (2) Competency assurance activities, including provider or health plan
36 performance evaluation, credentialing and accreditation;

37 (3) Conducting or arranging for medical reviews, audits or legal services,
38 including fraud and abuse detection and compliance programs;

39 (4) Specified insurance functions, such as underwriting, risk rating and
40 reinsuring risks;

