CHAPTER 1683

MAINE HEALTH DATA ORGANIZATION

SUBCHAPTER 1

GENERAL PROVISIONS

§8701. Declaration of purpose

It is the intent of the Legislature that uniform systems of reporting health care information be established; that all providers and payors who are required to file reports do so in a manner consistent with these systems; and that, using the least restrictive means practicable for the protection of privileged health care information, public access to those reports be ensured. [PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

SECTION HISTORY

PL 1995, c. 653, §A2 (NEW). PL 1995, c. 653, §A7 (AFF).

§8702. Definitions

(CONTAINS TEXT WITH VARYING EFFECTIVE DATES)

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings. [PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

1. Board. "Board" means the Board of Directors of the Maine Health Data Organization established pursuant to section 8703.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

1-A. Carrier. "Carrier" means an insurance company licensed in accordance with Title 24-A, including a health maintenance organization, a multiple employer welfare arrangement licensed pursuant to Title 24-A, chapter 81, a preferred provider organization, a fraternal benefit society or a nonprofit hospital or medical service organization or health plan licensed pursuant to Title 24. An employer exempted from the applicability of Title 24-A, chapter 56-A under the federal Employee Retirement Income Security Act of 1974, 29 United States Code, Sections 1001 to 1461 (1988) is not considered a carrier.
[PL 2001, c. 457, §1 (NEW).]

1-B. (TEXT EFFECTIVE ON CONTINGENCY: See PL 2013, c. 528, §12) Business associate. "Business associate" has the same meaning as under 45 Code of Federal Regulations, Section 160.103 (2013).
[PL 2013, c. 528, §2 (NEW); PL 2013, c. 528, §12 (AFF).]

2. Clinical data. "Clinical data" includes but is not limited to the data required to be submitted by providers and payors pursuant to sections 8708 and 8711.
[PL 2007, c. 136, §1 (AMD).]

2-A. (TEXT EFFECTIVE ON CONTINGENCY; See PL 2013, c. 528, §12) Covered entity. "Covered entity" has the same meaning as under 45 Code of Federal Regulations, Section 160.103 (2013).
[PL 2013, c. 528, §3 (NEW); PL 2013, c. 528, §12 (AFF).]

3. Financial data. "Financial data" includes but is not limited to financial information required to be submitted pursuant to section 8709.

[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

4. Health care facility. "Health care facility" means a public or private, proprietary or not-for-profit entity or institution providing health services, including, but not limited to, a radiological facility licensed under chapter 160, a health care facility licensed under chapter 405, an independent radiological service center, a federally qualified health center certified by the United States Department of Health and Human Services, Health Resources and Services Administration, a rural health clinic or rehabilitation agency certified or otherwise approved by the Division of Licensing and Regulatory Services within the Department of Health and Human Services, a home health care provider licensed under chapter 419, an assisted living facility or a residential care facility licensed under chapter 1663, a hospice provider licensed under chapter 1681, a state institution as defined under Title 34-B, chapter 1 and a mental health facility licensed under Title 34-B, chapter 1. For the purposes of this chapter, "health care facility" does not include retail pharmacies.
[PL 2023, c. 176, §36 (AMD).]

4-A. Health care practitioner. "Health care practitioner" has the meaning provided in Title 24, section 2502, subsection 1-A.
[PL 2003, c. 469, Pt. C, §18 (NEW).]

4-B. (TEXT EFFECTIVE ON CONTINGENCY: See PL 2013, c. 528, §12) HIPAA. "HIPAA" means the federal Health Insurance Portability and Accountability Act of 1996.
[PL 2013, c. 528, §4 (NEW); PL 2013, c. 528, §12 (AFF).]

5. Managed care organization. "Managed care organization" means an organization that manages and controls medical services, including but not limited to a health maintenance organization, a preferred provider organization, a competitive medical plan, a managed indemnity insurance program and a nonprofit hospital and medical service organization, licensed in the State.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

5-A. Medicare health plan sponsor. "Medicare health plan sponsor" means a health insurance carrier or other private company authorized by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services to administer Medicare Part C and Part D benefits under a health plan or prescription drug plan.
[PL 2009, c. 71, §4 (AMD).]

5-B. Nonlicensed carrier. "Nonlicensed carrier" means a health insurance carrier that is not required to obtain a license in accordance with Title 24-A and pays health care claims on behalf of residents of this State.
[PL 2007, c. 136, §1 (NEW).]

6. Organization. "Organization" means the Maine Health Data Organization established under this chapter.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

7. Outpatient services. "Outpatient services" means all therapeutic or diagnostic health care services rendered to a person who has not been admitted to a hospital as an inpatient.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

8. Payor. "Payor" means a 3rd-party payor, 3rd-party administrator, Medicare health plan sponsor, pharmacy benefits manager or nonlicensed carrier.
[PL 2009, c. 71, §5 (AMD).]

8-A. Plan sponsor. "Plan sponsor" means any person, other than an insurer, who establishes or maintains a plan covering residents of this State, including, but not limited to, plans established or maintained by 2 or more employers or jointly by one or more employers and one or more employee organizations or the association, committee, joint board of trustees or other similar group of representatives of the parties that establish or maintain the plan.

[PL 2001, c. 457, §3 (NEW).]

8-B. Pharmacy benefits manager. "Pharmacy benefits manager" has the same meaning as in Title 24-A, section 4347, subsection 17.
[PL 2019, c. 469, §2 (AMD); PL 2019, c. 469, §9 (AFF).]

8-C. (TEXT EFFECTIVE ON CONTINGENCY: See PL 2013, c. 528, §12) Protected health information. "Protected health information" includes:

A. "Protected health information" as defined in 45 Code of Federal Regulations, Section 160.103 (2013); [PL 2013, c. 528, §5 (NEW); PL 2013, c. 528, §12 (AFF).]

B. Individually identifiable health information:

(1) That is demographic information about an individual reported to the organization that relates to the past, present or future physical or mental health or condition of the individual;

(2) That pertains to the provision of health care to an individual; or

(3) That relates to the past, present or future payment for the provision of health care to an individual and that identifies, or with respect to which there is a reasonable basis to believe the information could be used to identify, the individual; and [PL 2013, c. 528, §5 (NEW); PL 2013, c. 528, §12 (AFF).]

C. "Health care information" as defined in section 1711-C, subsection 1, paragraph E. [PL 2013, c. 528, §5 (NEW); PL 2013, c. 528, §12 (AFF).]
[PL 2013, c. 528, §5 (NEW); PL 2013, c. 528, §12 (AFF).]

9. Provider. "Provider" means a health care facility, health care practitioner, health product manufacturer or health product vendor but does not include a retail pharmacy.
[PL 2011, c. 233, §2 (AMD).]

9-A. Quality data. "Quality data" means information on health care quality required to be submitted pursuant to section 8708-A.
[PL 2003, c. 469, Pt. C, §20 (NEW).]

10. Restructuring data. "Restructuring data" means reports, charts and information required to be submitted pursuant to section 8710.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

10-A. Third-party administrator. "Third-party administrator" means any person who, on behalf of a plan sponsor, health care service plan, nonprofit hospital or medical service organization, health maintenance organization or insurer, receives or collects charges, contributions or premiums for, or adjusts or settles claims on, residents of this State.
[PL 2001, c. 457, §3 (NEW).]

11. Third-party payor. "Third-party payor" means a health insurer, carrier, including a carrier that provides only administrative services for plan sponsors, nonprofit hospital, medical services organization or managed care organization licensed in the State. "Third-party payor" does not include carriers licensed to issue limited benefit health policies or accident, specified disease, vision, disability, long-term care or nursing home care policies.
[PL 2007, c. 695, Pt. A, §27 (RPR).]

SECTION HISTORY

PL 1995, c. 653, §A2 (NEW). PL 1995, c. 653, §A7 (AFF). PL 1997, c. 525, §1 (AMD). PL 1999, c. 353, §1 (AMD). PL 2001, c. 457, §§1-3 (AMD). PL 2001, c. 596, §B21 (AMD). PL 2001, c. 596, §B25 (AFF). PL 2001, c. 677, §2 (AMD). PL 2003, c. 469, §§C17-21 (AMD). PL 2003, c. 689, §B6 (REV). RR 2005, c. 2, §18 (COR). PL 2005, c. 253, §2 (AMD). PL 2007, c. 136, §1 (AMD). PL 2007, c. 240, Pt. VV, §2 (AMD). PL 2007, c. 466, Pt. B, §18 (AMD). PL

2007, c. 695, Pt. A, §§26, 27 (AMD). PL 2009, c. 71, §§4, 5 (AMD). PL 2011, c. 233, §§1, 2 (AMD). PL 2011, c. 443, §3 (AMD). PL 2013, c. 528, §§2-5 (AMD). PL 2013, c. 528, §12 (AFF). PL 2019, c. 469, §2 (AMD). PL 2019, c. 469, §9 (AFF). PL 2023, c. 176, §36 (AMD).

§8703. Maine Health Data Organization established

The Maine Health Data Organization is established as an independent executive agency. [PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

1. Objective. 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 this chapter. 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. [PL 2021, c. 423, Pt. A, §5 (AMD).]

2. Board of directors. The organization operates under the supervision of a board of directors, which consists of 20 voting members and one nonvoting member.

A. The Governor shall appoint 18 board members in accordance with the following requirements. Appointments by the Governor are not subject to review or confirmation.

(1) Four members must represent consumers. For the purposes of this section, "consumer" means a person who is not affiliated with or employed by a 3rd-party payor, a provider or an association representing those providers or those 3rd-party payors.

(2) Three members must represent employers. One member must be chosen from a list provided by a health management coalition in this State. One member must be chosen from a list provided by a statewide chamber of commerce.

(3) Two members must represent 3rd-party payors chosen from a list provided by a statewide organization representing 3rd-party payors.

(4) Nine members must represent providers. Two provider members must represent hospitals chosen from a list provided by the Maine Hospital Association. Two provider members must be physicians or representatives of physicians, one chosen from a list provided by the Maine Medical Association and one chosen from a list provided by the Maine Osteopathic Association. One provider member must be a doctor of chiropractic chosen from a list provided by a statewide chiropractic association. One provider member must be a representative, chosen from a list provided by the Maine Primary Care Association, of a federally qualified health center. One provider member must be a pharmacist chosen from a list provided by the Maine Pharmacy Association. One provider member must be a mental health provider chosen from a list provided by the Maine Association of Mental Health Services. One provider member must represent a home health care company. [PL 2007, c. 136, §2 (AMD).]

B. The commissioner shall appoint one member who is an employee of the department to represent the State's interest in maintaining health data and to ensure that information collected is available for determining public health policy. [PL 2009, c. 71, §6 (AMD).]

C. [PL 1999, c. 353, §4 (RP).]

D. The Executive Director of Dirigo Health, or a designee of the executive director who is an employee of Dirigo Health, shall serve as a voting member. [PL 2009, c. 71, §6 (NEW).]

E. The Commissioner of Professional and Financial Regulation, or the commissioner's designee who is an employee of the Department of Professional and Financial Regulation, shall serve in a nonvoting, consultative capacity. [PL 2009, c. 71, §6 (NEW).]

[PL 2009, c. 71, §6 (AMD).]

3. Terms of office. The terms of office of board members are determined under this subsection.

A. The terms of board members appointed by the Governor are determined as follows.

(1) Initial terms are staggered. One consumer, one employer, one 3rd-party payor and 3 providers shall serve one-year terms. Two consumers, one employer, one 3rd-party payor and 3 providers shall serve 2-year terms.

(2) After the initial terms, members appointed by the Governor shall serve full 3-year terms and shall continue to serve until their successors have been appointed.

(3) Board members may serve 3 full terms consecutively. [PL 2005, c. 253, §4 (AMD).]

B. State agency board members may serve an unlimited number of terms. [PL 2009, c. 71, §7 (AMD).]

[PL 2009, c. 71, §7 (AMD).]

4. Meetings; officers. Board members shall elect a chair and a vice-chair from among the membership to serve 2-year terms. All meetings of the board are public proceedings within the meaning of the Freedom of Access Law, Title 1, chapter 13, subchapter I.

[PL 1999, c. 353, §5 (AMD).]

5. Legal counsel. The Attorney General, when requested, shall furnish any legal assistance, counsel or advice the organization requires in the discharge of its duties.

[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

6. Compensation. Board members are entitled to reimbursement for necessary expenses according to the provisions of Title 5, chapter 379.

[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

SECTION HISTORY

PL 1995, c. 653, §A2 (NEW). PL 1995, c. 653, §A7 (AFF). PL 1997, c. 53, §1 (AMD). PL 1997, c. 568, §1 (AMD). PL 1999, c. 353, §§2-5 (AMD). PL 2001, c. 457, §§4-6 (AMD). PL 2003, c. 264, §1 (AMD). PL 2003, c. 469, §C22 (AMD). PL 2005, c. 253, §§3,4 (AMD). PL 2007, c. 136, §2 (AMD). PL 2009, c. 71, §§6, 7 (AMD). PL 2019, c. 470, §1 (AMD). PL 2021, c. 423, Pt. A, §5 (AMD).

§8704. Powers and duties of the board

The board has the following powers and duties. [PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

1. Uniform reporting systems. The board shall establish uniform reporting systems.

A. The board shall develop and implement policies and procedures for the collection, processing, storage and analysis of clinical, financial, quality and provider data and prescription drug price data in accordance with this subsection for the following purposes:

(1) To use, build and improve upon and coordinate existing data sources and measurement efforts through the integration of data systems and standardization of concepts;

(2) To coordinate the development of a linked public and private sector information system;

(3) To emphasize data that is useful, relevant and not duplicative of existing data;

(4) To minimize the burden on those providing data; and

(5) To preserve the reliability, accuracy and integrity of collected data while ensuring that the data is available in the public domain. [PL 2021, c. 423, Pt. B, §2 (AMD).]

B. Information and data required to be filed pursuant to this chapter must be filed annually or more frequently as specified by the organization. The organization shall establish a schedule for

compliance with the required uniform reporting systems. [PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

C. The organization may modify the uniform reporting systems for clinical, financial, quality and restructuring data to allow for differences in the scope or type of services and in financial structure among health care facilities, providers or payors subject to this chapter. [PL 2003, c. 469, Pt. C, §24 (AMD).]

D. The board may provide analysis of data upon request. [PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

E. The board shall exempt from reporting by a provider data regarding a person who informs the provider of the person's objection, or the objection of a parent of a minor, to inclusion in data collection based on a sincerely held religious belief. [PL 1999, c. 353, §7 (NEW).]

[PL 2021, c. 423, Pt. B, §2 (AMD).]

2. Contracts for data collection; processing. The board may contract with one or more qualified, nongovernmental, independent 3rd parties for services necessary to carry out the data collection, processing and storage activities required under this chapter. For purposes of this subsection, a group or organization affiliated with the University of Maine System is not considered a governmental entity. Unless permission is specifically granted by the board, a 3rd party hired by the organization may not release, publish or otherwise use any information to which the 3rd party has access under its contract and shall otherwise comply with the requirements of this chapter.

[PL 2001, c. 457, §8 (AMD).]

3. Contracts generally. The board may enter into all other contracts necessary or proper to carry out the powers and duties of this chapter, including contracts allowing organization staff to provide technical assistance to other public or private entities, with the proceeds used to offset the operational costs of the organization.

[PL 2007, c. 136, §3 (AMD).]

4. Rulemaking. The board shall adopt rules necessary for the proper administration and enforcement of the requirements of this chapter. All rules must be adopted in accordance with Title 5, chapter 375 and unless otherwise provided are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

[PL 2011, c. 494, §7 (AMD).]

5. Public hearings. The board may conduct any public hearings determined necessary to carry out its responsibilities.

[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

6. Staff. The board shall appoint staff as needed to carry out the duties and responsibilities of the board under this chapter. The appointment and compensation of the staff are subject to Civil Service Law.

[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

7. Annual report. The board shall prepare and submit an annual report on the operation of the organization, including any activity contracted for by the organization, with resulting net earnings, as well as on collaborative activities with other health data collection and management organizations and stakeholder groups on their efforts to improve consumer access to health care quality and price information and price transparency initiatives, to the Governor and the joint standing committee of the Legislature having jurisdiction over health and human services matters and the joint standing committee of the Legislature having jurisdiction over insurance and financial services matters no later than February 1st of each year. The report must include an annual accounting of all revenue received and expenditures incurred in the previous year and all revenue and expenditures planned for the next year.

The report must include a list of persons or entities that requested data from the organization in the preceding year with a brief summary of the stated purpose of the request.
[PL 2015, c. 494, Pt. A, §26 (AMD).]

8. Grants. The board may solicit, receive and accept grants, funds or anything of value from any public or private organization and receive and accept contributions of money, property, labor or any other thing of value from any legitimate source, except that the board may not accept grants from any entity that might have a vested interest in the decisions of the board.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

9. Cooperation; advice. The board may cooperate with and advise the department and any other person or entity on behavioral risk factor surveys, work site health and safety, and health work force research.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

10. Quality improvement foundations.
[PL 2003, c. 469, Pt. C, §26 (RP).]

11. Other powers. The board may exercise all powers reasonably necessary to carry out the powers expressly granted and responsibilities expressly imposed by this chapter.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

SECTION HISTORY

PL 1995, c. 653, §A2 (NEW). PL 1995, c. 653, §A7 (AFF). PL 1997, c. 525, §2 (AMD). PL 1999, c. 127, §B8 (AMD). PL 1999, c. 353, §§6-8 (AMD). PL 2001, c. 457, §§7-10 (AMD). PL 2003, c. 469, §§C23-26 (AMD). PL 2005, c. 253, §5 (AMD). PL 2005, c. 565, §5 (AMD). PL 2007, c. 136, §3 (AMD). PL 2007, c. 460, §§2, 3 (AMD). PL 2011, c. 494, §§7, 8 (AMD). PL 2013, c. 560, §3 (AMD). PL 2015, c. 494, Pt. A, §26 (AMD). PL 2019, c. 470, §2 (AMD). PL 2021, c. 423, Pt. B, §2 (AMD).

§8705. Enforcement

(REPEALED)

SECTION HISTORY

PL 1995, c. 653, §A2 (NEW). PL 1995, c. 653, §A7 (AFF). PL 1999, c. 353, §9 (AMD). PL 2001, c. 457, §§11,12 (AMD). PL 2003, c. 452, §§K28,29 (AMD). PL 2003, c. 452, §X2 (AFF). PL 2003, c. 659, §1 (RP).

§8705-A. Enforcement

(CONTAINS TEXT WITH VARYING EFFECTIVE DATES)

(TEXT EFFECTIVE UNTIL CONTINGENCY: See PL 2013, c. 528, §12) The board shall adopt rules to ensure that payors, providers, prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers file data as required by section 8704, subsection 1; that users that obtain health data and information from the organization safeguard the identification of patients and health care practitioners as required by section 8707, subsections 1 and 3; and that payors, providers, prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers pay all assessments as required by section 8706, subsection 2. [PL 2019, c. 470, §3 (AMD).]

(TEXT EFFECTIVE ON CONTINGENCY: See PL 2013, c. 528, §12) The board shall adopt rules to ensure that payors, providers, prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers file data as required by section 8704, subsection 1; that users that obtain health data and information from the organization safeguard the identification of patients and health care practitioners as required by section 8714, subsections 2, 3 and 4; and that payors, providers,

prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers pay all assessments as required by section 8706, subsection 2. [PL 2019, c. 470, §4 (AMD).]

1. Definitions. As used in this section, unless the context otherwise indicates, the following definitions of "intentionally" and "knowingly" apply to this section.

A. A person acts intentionally with respect to a result of that person's conduct when it is that person's conscious object to produce such a result. [PL 2003, c. 659, §2 (NEW).]

B. A person acts knowingly with respect to a result of that person's conduct when the person is aware that it is practically certain that that person's conduct will cause such a result. [PL 2003, c. 659, §2 (NEW).]

[PL 2003, c. 659, §2 (NEW).]

2. Rulemaking. The board shall adopt rules to implement this section. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A. The rules may contain procedures for monitoring compliance with this chapter. Rules adopted pursuant to this subsection must include a schedule of fines for:

A. Failure to file data; [PL 2003, c. 659, §2 (NEW).]

B. Failure to pay assessments; and [PL 2003, c. 659, §2 (NEW).]

C. Intentionally or knowingly and without authorization using or disseminating health care information that directly or indirectly identifies patients or health care practitioners performing abortions as defined in section 1596. [PL 2003, c. 659, §2 (NEW).]

[PL 2003, c. 659, §2 (NEW).]

3. (TEXT EFFECTIVE UNTIL CONTINGENCY: See PL 2013, c. 528, §12) Fines. The following provisions apply to enforcement actions under this section except for circumstances beyond a person's or entity's control.

A. When a person or entity that is a health care facility, payor, prescription drug manufacturer, wholesale drug distributor or pharmacy benefits manager violates the requirements of this chapter, except for section 8707, that person or entity commits a civil violation for which a fine of not more than $1,000 per day may be adjudged. A fine imposed under this paragraph may not exceed $25,000 for any one occurrence. [PL 2019, c. 470, §5 (AMD).]

B. A person or entity that receives data or information under the terms and conditions of section 8707 and intentionally or knowingly uses, sells or transfers the data in violation of the board's rules for commercial advantage, pecuniary gain, personal gain or malicious harm commits a civil violation for which a fine not to exceed $500,000 may be adjudged. [PL 2005, c. 565, §6 (AMD).]

C. A person or entity not covered by paragraph A or B that violates the requirements of this chapter, except for section 8707, commits a civil violation for which a fine of not more than $100 per day may be adjudged. A fine imposed under this paragraph may not exceed $2,500 for any one occurrence. [PL 2003, c. 659, §2 (NEW).]

[PL 2019, c. 470, §5 (AMD).]

3. (TEXT EFFECTIVE ON CONTINGENCY: See PL 2013, c. 528, §12) Fines. The following provisions apply to enforcement actions under this section except for circumstances beyond a person's or entity's control.

A. When a person or entity that is a health care facility, payor, prescription drug manufacturer, wholesale drug distributor or pharmacy benefits manager violates the requirements of this chapter, except for section 8714, that person or entity commits a civil violation for which a fine of not more than $1,000 per day may be adjudged. A fine imposed under this paragraph may not exceed $25,000 for any one occurrence. [PL 2019, c. 470, §6 (AMD).]

B. A person or entity that receives data or information under the terms and conditions of section 8714 and intentionally or knowingly uses, sells or transfers the data in violation of the board's rules for commercial advantage, pecuniary gain, personal gain or malicious harm commits a civil violation for which a fine not to exceed $500,000 may be adjudged. [PL 2013, c. 528, §7 (AMD); PL 2013, c. 528, §12 (AFF).]

C. A person or entity not covered by paragraph A or B that violates the requirements of this chapter, except for section 8714, commits a civil violation for which a fine of not more than $100 per day may be adjudged. A fine imposed under this paragraph may not exceed $2,500 for any one occurrence. [PL 2013, c. 528, §7 (AMD); PL 2013, c. 528, §12 (AFF).]

[PL 2019, c. 470, §6 (AMD).]

4. Enforcement action. Upon a finding that a person or entity has failed to comply with the requirements of this chapter, including the payment of a fine determined under this section, the board may undertake any or all of the following.

A. The board may refer the matter to the department or board that issued a license to the provider for such action as the department or board considers appropriate. [PL 2003, c. 659, §2 (NEW).]

B. The board may refer the matter to the Department of Professional and Financial Regulation, Bureau of Insurance for such action against the payor as the bureau considers appropriate. [PL 2003, c. 659, §2 (NEW).]

C. The board may file a complaint with the Superior Court in the county in which the person resides or the entity is located or in Kennebec County seeking an order to require that person or entity to comply with the requirements of this chapter, seeking enforcement of a fine determined under this section or seeking other relief from the court. [PL 2003, c. 659, §2 (NEW).]

[PL 2003, c. 659, §2 (NEW).]

5. Injunctive relief. In the event of any violation of this chapter or any rule adopted pursuant to this chapter, the Attorney General may seek to enjoin a further violation and seek any other appropriate remedy provided by this chapter.

[PL 2003, c. 659, §2 (NEW).]

6. Exception.

[PL 2009, c. 613, §7 (NEW); MRSA T. 22 §8705-A, sub-§6 (RP).]

SECTION HISTORY

PL 2003, c. 659, §2 (NEW). PL 2005, c. 565, §6 (AMD). PL 2007, c. 136, §4 (AMD). PL 2009, c. 613, §7 (AMD). PL 2013, c. 528, §§6, 7 (AMD). PL 2013, c. 528, §12 (AFF). PL 2019, c. 470, §§3-6 (AMD).

§8706. Revenues and expenditures

1. Transition funding.

[PL 1999, c. 353, §10 (RP).]

2. Permanent funding. Permanent funding for the organization is provided from reasonable costs, user fees and assessments according to this subsection and as provided by rules adopted by the board.

A. Fees may be charged for the reasonable costs of duplicating, mailing, publishing and supplies. [PL 1997, c. 525, §3 (RPR).]

B. Reasonable user fees must be charged on a sliding scale for the right to access and use the health data and information available from the organization. Fees may be charged for services provided to the department on a contractual basis. Fees may be reduced or waived for users that demonstrate a plan to use the data or information in research of general value to the public health or inability to pay the scheduled fees, as provided by rules adopted by the board. [PL 2005, c. 253, §6 (AMD).]

C. The operations of the organization must be supported from 4 sources as provided in this paragraph:

(1) Fees collected pursuant to paragraphs A and B;

(2) Annual assessments of not less than $100 assessed against the following entities licensed under Titles 24 and 24-A: nonprofit hospital and medical service organizations, health insurance carriers and health maintenance organizations on the basis of the total annual health care premium; and 3rd-party administrators, carriers that provide only administrative services for a plan sponsor and pharmacy benefits managers that process and pay claims on the basis of claims processed or paid for each plan sponsor. The assessments are to be determined on an annual basis by the board. Health care policies issued for specified disease, accident, injury, hospital indemnity, disability, long-term care or other limited benefit health insurance policies are not subject to assessment under this subparagraph. For purposes of this subparagraph, policies issued for dental services are not considered to be limited benefit health insurance policies. The total dollar amount of assessments under this subparagraph must equal the assessments under subparagraph (3);

(3) Annual assessments of not less than $100 assessed by the organization against providers. The assessments are to be determined on an annual basis by the board. The total dollar amount of assessments under this subparagraph must equal the assessments under subparagraph (2); and

(4) Annual assessments of $500 assessed by the organization against prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers.

The aggregate level of annual assessments under subparagraphs (2), (3) and (4) must be an amount sufficient to meet the organization's expenditures authorized in the state budget established under Title 5, chapter 149. The board may waive assessments otherwise due under subparagraphs (2), (3) and (4) when a waiver is determined to be in the interests of the organization and the parties to be assessed. [PL 2019, c. 470, §7 (AMD).]

[PL 2019, c. 470, §7 (AMD).]

3. Use of funds. The organization shall use the revenues from fees, assessments and user fees to defray the costs incurred by the board pursuant to this chapter, including staff salaries, administrative expenses, data system expenses, consulting fees and any other reasonable costs incurred to administer this chapter.

[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

4. Budget. The expenditures of the organization are subject to legislative approval in the biennial budget process.

[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

5. Unexpended funds. Any funds not expended at the end of a fiscal year may not lapse but must be carried forward to the succeeding fiscal year.

[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

6. Deposit with Treasurer of State. The organization shall deposit all payments made pursuant to this section with the Treasurer of State into a dedicated account. The deposits must be used for the sole purpose of paying the expenses of the organization.

[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

SECTION HISTORY

PL 1995, c. 653, §A2 (NEW). PL 1995, c. 653, §A7 (AFF). PL 1997, c. 525, §3 (AMD). PL 1999, c. 353, §§10,11 (AMD). PL 2001, c. 457, §13 (AMD). PL 2005, c. 253, §6 (AMD). PL 2005, c. 565, §7 (AMD). PL 2007, c. 136, §5 (AMD). PL 2019, c. 470, §7 (AMD).

§8707. Public access to data

(CONTAINS TEXT WITH VARYING EFFECTIVE DATES)

(WHOLE SECTION TEXT EFFECTIVE UNTIL CONTINGENCY: See PL 2013, c. 528, §12)

The board shall adopt rules to provide for public access to data and to implement the requirements of this section. [PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

1. Public access; confidentiality. The board shall adopt rules making available to any person, upon request, information, except privileged medical information and confidential information, provided to the organization under this chapter as long as individual patients are not directly or indirectly identified through a reidentification process. The board shall adopt rules to protect the identity of certain health care practitioners, as it determines appropriate, except that the identity of practitioners performing abortions as defined in section 1596 must be designated as confidential and must be protected. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter II-A.
[PL 2001, c. 457, §14 (AMD).]

2. Notice and comment period. The rules must establish criteria for determining whether information is confidential clinical data, confidential financial data or privileged medical information and adopt procedures to give affected health care providers and payors notice and opportunity to comment in response to requests for information that may be considered confidential or privileged.
[PL 2003, c. 469, Pt. C, §27 (AMD).]

3. Public health studies. The rules may allow exceptions to the confidentiality requirements only to the extent authorized in this subsection.

A. The board may approve access to identifying information for patients to the department and other researchers with established protocols that have been approved by the board for safeguarding confidential or privileged information. [PL 2001, c. 457, §15 (AMD).]

B. The rules must ensure that:

(1) Identifying information is used only to gain access to medical records and other medical information pertaining to public health;

(2) Medical information about any patient identified by name is not obtained without the consent of that patient except when the information sought pertains only to verification or comparison of health data and the board finds that confidentiality can be adequately protected without patient consent;

(3) Those persons conducting the research or investigation do not disclose medical information about any patient identified by name to any other person without that patient's consent;

(4) Those persons gaining access to medical information about an identified patient use that information to the minimum extent necessary to accomplish the purposes of the research for which approval was granted; and

(5) The protocol for any research is designed to preserve the confidentiality of all health care information that can be associated with identified patients, to specify the manner in which contact is made with patients and to maintain public confidence in the protection of confidential information. [PL 2001, c. 457, §15 (AMD).]

C. The board may not grant approval under this subsection if the board finds that the proposed identification of or contact with patients would violate any state or federal law or diminish the confidentiality of health care information or the public's confidence in the protection of that information in a manner that outweighs the expected benefit to the public of the proposed investigation. [PL 2001, c. 457, §15 (AMD).]

[PL 2001, c. 457, §15 (AMD).]

4. Certain confidential information. The board may determine financial data submitted to the organization under section 8709 to be confidential information if the public disclosure of the data will directly result in the provider of the data being placed in a competitive economic disadvantage. This section may not be construed to relieve the provider of the data of the requirement to disclose such information to the organization in accordance with this chapter and rules adopted by the board.
[PL 2011, c. 524, §4 (AMD).]

5. Rules for release, publication and use of data. The rules must govern the release, publication and use of analyses, reports or compilations derived from the health data made available by the organization.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

SECTION HISTORY

PL 1995, c. 653, §A2 (NEW). PL 1995, c. 653, §A7 (AFF). PL 1999, c. 353, §§12,13 (AMD). PL 2001, c. 457, §§14,15 (AMD). PL 2003, c. 469, §C27 (AMD). PL 2007, c. 466, Pt. A, §44 (AMD). PL 2011, c. 524, §4 (AMD). PL 2013, c. 528, §8 (RP). PL 2013, c. 528, §12 (AFF).

§8707. Public access to data

(CONTAINS TEXT WITH VARYING EFFECTIVE DATES)

(WHOLE SECTION TEXT REPEALED ON CONTINGENCY: See PL 2013, c. 528, §12)

(REPEALED)

SECTION HISTORY

PL 1995, c. 653, §A2 (NEW). PL 1995, c. 653, §A7 (AFF). PL 1999, c. 353, §§12,13 (AMD). PL 2001, c. 457, §§14,15 (AMD). PL 2003, c. 469, §C27 (AMD). PL 2007, c. 466, Pt. A, §44 (AMD). PL 2011, c. 524, §4 (AMD). PL 2013, c. 528, §8 (RP). PL 2013, c. 528, §12 (AFF).

§8708. Clinical data

Clinical data must be filed, stored and managed as follows. [PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

1. Information required. Pursuant to rules adopted by the board for form, medium, content and time for filing, each health care facility shall file with the organization the following information:

A. [PL 1999, c. 353, §14 (RP).]

B. A completed uniform hospital discharge data set, or comparable information, for each patient discharged from the facility after June 30, 1983 and for each hospital outpatient service occurring after June 30, 1996; and [PL 1999, c. 353, §14 (AMD).]

C. In addition to any other requirements applicable to specific categories of health care facilities, the organization may require the filing of data as set forth in this chapter or in rules adopted pursuant to this chapter. [PL 1999, c. 353, §14 (AMD).]
[PL 1999, c. 353, §14 (AMD).]

2. Additional information on ambulatory services and surgery. Pursuant to rules adopted by the board for form, medium, content and time for filing, each provider shall file with the organization a completed data set, comparable to data filed by health care facilities under subsection 1, paragraph B. This subsection may not be construed to require duplication of information required to be filed under subsection 1.
[PL 2001, c. 457, §16 (AMD).]

3. More than one licensed health care facility or location. When more than one licensed health care facility is operated by the reporting organization, the information required by this chapter must be

reported for each health care facility separately. When a provider of health care operates in more than one location, the organization may require that information be reported separately for each location.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

4. Data lists.
[PL 2001, c. 457, §17 (RP).]

5. Medical record abstract data. In addition to the information required to be filed under subsections 1 and 2 and pursuant to rules adopted by the organization for form, medium, content and time of filing, each health care facility shall file with the organization such medical record abstract data as the organization may require.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

6. Merged data. The board may require the discharge data submitted pursuant to subsection 1 and any medical record abstract data required pursuant to subsection 5 to be merged with associated billing data.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

6-A. Additional data. Subject to the limitations of section 8704, subsection 1, the board may adopt rules requiring the filing of additional clinical data from other providers and payors as long as the submission of data to the organization is consistent with federal law. Data filed by payors must be provided in a format that does not directly identify the patient.
[PL 2007, c. 136, §6 (AMD).]

7. Authority to obtain information. Nothing in this section may be construed to limit the board's authority to obtain information that it considers necessary to carry out its duties. The board shall adopt rules regarding the definition, collection, use and release of clinical data before collecting any type of clinical data that it did not collect as of March 1, 2014. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A.
[PL 2013, c. 528, §9 (AMD).]

SECTION HISTORY

PL 1995, c. 653, §A2 (NEW). PL 1995, c. 653, §A7 (AFF). PL 1997, c. 525, §4 (AMD). PL 1999, c. 353, §14 (AMD). PL 2001, c. 457, §§16-18 (AMD). PL 2007, c. 136, §6 (AMD). PL 2013, c. 528, §9 (AMD).

§8708-A. Quality data

The board shall adopt rules regarding the collection of quality data. The board shall work with the Maine Quality Forum and the Maine Quality Forum Advisory Council established in Title 24-A, chapter 87, subchapter 2 to develop the rules. The rules must be based on the quality measures adopted by the Maine Quality Forum pursuant to Title 24-A, section 6951, subsection 2. The rules must specify the content, form, medium and frequency of quality data to be submitted to the organization. In the collection of quality data, the organization must minimize duplication of effort, minimize the burden on those required to provide data and focus on data that may be retrieved in electronic format from within a health care practitioner's office or health care facility. As specified by the rules, health care practitioners and health care facilities shall submit quality data to the organization. Rules adopted pursuant to this section are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A.
[PL 2003, c. 469, Pt. C, §28 (NEW).]

SECTION HISTORY

PL 2003, c. 469, §C28 (NEW).

§8709. Financial data; scope of service data

Financial data and scope of service data must be filed, stored and managed as follows. [PL 1999, c. 353, §15 (AMD).]

1. Financial data. Each health care facility shall file with the organization, in a form specified by rule pursuant to section 8704, financial information including costs of operation, revenues, assets, liabilities, fund balances, other income, rates, charges and units of services, except to the extent that the board specifies by rule that portions of this information are unnecessary.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

1-A. Hospitals; standardized accounting template. When filing the financial information required under subsection 1, a hospital also shall file information using the standardized accounting template published in the report of the Commission to Study Maine's Community Hospitals in February 2005. The hospital shall file this information using an electronic version of the template provided to the hospital by the organization. If in succeeding years the template needs to be modified, the board shall adopt rules specifying the filing requirements. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.
[PL 2005, c. 394, §2 (NEW).]

2. Certification required. The board may require certification of such financial reports and attestation from responsible officials of the health care facility that such reports have to the best of their knowledge and belief been prepared in accordance with the requirements of the board.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

3. Scope of service data. Each health care facility shall file with the organization scope of service information, including bed capacity by service provided, special services, ancillary services, physician profiles in the aggregate by clinical specialties, nursing services and such other scope of service information as the organization determines necessary for the performance of its duties.
[PL 1999, c. 353, §15 (NEW).]

SECTION HISTORY

PL 1995, c. 653, §A2 (NEW). PL 1995, c. 653, §A7 (AFF). PL 1999, c. 353, §15 (AMD). PL 2005, c. 394, §2 (AMD).

§8710. Restructuring data

Restructuring data must be filed, stored and managed as follows. [PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

1. Major structural changes. The board may require providers and payors to report the occurrence of major structural changes relevant to the restructuring of the delivery and financing of health care in the State and to the potential effects of that restructuring upon consumers.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

2. Rulemaking. The board shall adopt rules to define the specific structural changes to be reported, consistent with subsection 1. The required report must be limited to the filing of a concise narrative description of those occurrences that are clearly defined by the rule as requiring a report, accompanied by a chart depicting the relationship among organizations affected by the structural change. The rule must allow a single report to be filed by all providers and payors participating in or affected by a structural change for which a report is required.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

3. Additional information. In addition to the reports required under subsections 1 and 2, the organization may collect, store and analyze additional information from published sources and information that a provider or payor has prepared voluntarily for nonconfidential distribution to persons other than employees, officers and the governing body of the provider or payor.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

4. Construction. Nothing in this section may be construed to require providers or payors to notify the organization prior to taking action to evaluate restructuring or to require providers or payors to

generate, compile, analyze or submit information in addition to the concise narrative descriptions and chart required in subsection 2.
[PL 1995, c. 653, Pt. A, §2 (NEW); PL 1995, c. 653, Pt. A, §7 (AFF).]

SECTION HISTORY

PL 1995, c. 653, §A2 (NEW). PL 1995, c. 653, §A7 (AFF).

§8711. Other health care information

1. Development of health care information systems. In addition to its authority to obtain information to carry out the specific provisions of this chapter, the organization may require providers and payors to furnish information with respect to the nature and quantity of services or coverage provided to the extent necessary to develop proposals for the modification, refinement or expansion of the systems of information disclosure established under this chapter. The organization's authority under this subsection includes the design and implementation of pilot information reporting systems affecting selected categories or representative samples of providers and payors.
[PL 2007, c. 136, §7 (AMD).]

2. Information on mandated services.

[PL 2005, c. 253, §7 (RP).]

SECTION HISTORY

PL 1995, c. 653, §A2 (NEW). PL 1995, c. 653, §A7 (AFF). PL 1999, c. 353, §16 (AMD). PL 2001, c. 457, §19 (AMD). PL 2005, c. 253, §7 (AMD). PL 2007, c. 136, §7 (AMD).

§8712. Reports

The organization shall produce clearly labeled and easy-to-understand reports as follows. Unless otherwise specified, the organization shall distribute the reports on a publicly accessible site on the Internet or via mail or e-mail, through the creation of a list of interested parties. The organization shall make reports available to members of the public upon request. [PL 2009, c. 613, §8 (AMD).]

1. Quality. The organization shall promote public transparency of the quality and cost of health care in the State in conjunction with the Maine Quality Forum established in Title 24-A, section 6951 and shall collect, synthesize and publish information and reports on an annual basis that are easily understandable by the average consumer and in a format that allows the user to compare the information listed in this section to the extent practicable. The organization's publicly accessible websites and reports must, to the extent practicable, coordinate, link and compare information regarding health care services, their outcomes, the effectiveness of those services, the quality of those services by health care facility and by individual practitioner and the location of those services. The organization's health care costs website must provide a link in a publicly accessible format to provider-specific information regarding quality of services required to be reported to the Maine Quality Forum.
[RR 2009, c. 2, §63 (COR).]

2. Payments. The organization shall create a publicly accessible interactive website that presents reports related to payments for services rendered by health care facilities and practitioners to residents of the State. The services presented must include, but not be limited to, imaging, preventative health, radiology, surgical services, ambulance services, comparable health care services as defined in Title 24-A, section 4318-A, subsection 1, paragraph A and other services that are predominantly elective and may be provided to a large number of patients who do not have health insurance or are underinsured. The website must also be constructed to display prices paid by individual commercial health insurance companies, 3rd-party administrators and, unless prohibited by federal law, governmental payors. Beginning October 1, 2012, price information posted on the website must be posted semiannually and beginning October 1, 2022 must be posted annually, must display the date of posting and, when posted, must be current to within 12 months of the date of submission of the information. Payment reports and

price information posted on the website must include data submitted by payors with regard to all health care facilities and practitioners that provide comparable health care services as defined in Title 24-A, section 4318-A, subsection 1, paragraph A or services for which the organization reports data pertaining to the statewide average price pursuant to this subsection or Title 24-A, section 4318-B. Upon notice made by a health care facility or practitioner that data posted by the organization pertaining to that facility or practitioner is inaccurate or incomplete, the organization shall remedy the inaccurate or incomplete data within the earlier of 30 days of receipt of the notice and the next posting date.

A. [PL 2009, c. 613, §8 (RP).]

[PL 2023, c. 468, §1 (AMD).]

2-A. Facility fees charged by health care providers. By January 1, 2024, and annually thereafter, the organization shall produce and post on its publicly accessible website a report on the payments for facility fees made by payors to the extent that payment information is already reported to the organization. The organization shall submit the report required by this subsection to the Office of Affordable Health Care established in Title 5, section 3122 and the joint standing committee of the Legislature having jurisdiction over health data reporting and health insurance matters. The joint standing committee may report out legislation based on the report to a first regular or second regular session of the Legislature, depending on the year in which the report is submitted. The organization shall produce and post on its publicly accessible website information designed to educate the public about facility fees and whether and under what circumstances depending on payor and type of service a facility fee may be charged.

For the purposes of this subsection, unless the context otherwise indicates, the following terms have the following meanings.

A. "Facility fee" means any fee charged or billed by a health care provider for outpatient services provided in a hospital-based facility or freestanding emergency facility that is intended to compensate the health care provider for the operational expenses of the health care provider, separate and distinct from a professional fee, and charged or billed regardless of how a health care service is provided. [PL 2023, c. 410, §1 (NEW).]

B. "Health care provider" means a person, whether for profit or nonprofit, that furnishes bills or is paid for health care service delivery in the normal course of business. "Health care provider" includes, but is not limited to, a health system, hospital, hospital-based facility, freestanding emergency facility or urgent care clinic. [PL 2023, c. 410, §1 (NEW).]

[PL 2023, c. 672, §5 (AMD).]

3. Comparison report.

[PL 2021, c. 423, Pt. A, §7 (RP).]

4. Physician services.

[PL 2021, c. 423, Pt. A, §8 (RP).]

5. Prescription drug information. By December 1, 2018 and annually thereafter, the organization shall provide a report containing the following information about prescription drugs, both brand name and generic:

A. The 25 most frequently prescribed drugs in the State; [PL 2017, c. 406, §1 (NEW).]

B. The 25 costliest drugs as determined by the total amount spent on those drugs in the State; and [PL 2017, c. 406, §1 (NEW).]

C. The 25 drugs with the highest year-over-year cost increases as determined by the total amount spent on those drugs in the State. [PL 2017, c. 406, §1 (NEW).]

[PL 2017, c. 406, §1 (NEW).]

6. Data shared with Maine Prescription Drug Affordability Board. The organization may share data collected under this chapter with the Maine Prescription Drug Affordability Board, established under Title 5, section 12004-G, subsection 14-I, as long as any data shared pursuant to this subsection is not further disseminated.
[PL 2019, c. 471, §3 (NEW).]

SECTION HISTORY

PL 2003, c. 469, §C29 (NEW). PL 2005, c. 391, §2 (AMD). RR 2009, c. 2, §63 (COR). PL 2009, c. 71, §8 (AMD). PL 2009, c. 350, Pt. A, §1 (AMD). PL 2009, c. 613, §8 (AMD). PL 2011, c. 525, §1 (AMD). PL 2017, c. 232, §2 (AMD). PL 2017, c. 406, §1 (AMD). PL 2019, c. 471, §3 (AMD). PL 2021, c. 423, Pt. A, §§6-8 (AMD). PL 2023, c. 410, §1 (AMD). PL 2023, c. 468, §1 (AMD). PL 2023, c. 672, §5 (AMD).

§8713. Confidentiality protection for certain health care practitioners

(REPEALED)

SECTION HISTORY

PL 2007, c. 460, §4 (NEW). PL 2011, c. 494, §9 (RP).

§8714. General public access to data; rules

(CONTAINS TEXT WITH VARYING EFFECTIVE DATES)

(WHOLE SECTION TEXT EFFECTIVE ON CONTINGENCY: See PL 2013, c. 528, §12)

The board shall adopt rules to provide for public access to data allowed under this chapter and to implement the requirements of this section. [PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

1. Confidentiality. All data collected by the organization that contain protected health information are confidential. Data of the organization may be collected, stored and released only in accordance with this chapter and rules adopted pursuant to this chapter. Data of the organization containing protected health information may not be open to public inspection, are not public records for purposes of any state or federal freedom of access laws and may not be examined in any judicial, executive, legislative, administrative or other proceeding as to the existence or content of any individual's identifying health information except that an individual's identifying health information may be used to the extent necessary to prosecute civil or criminal violations regarding information in the organization database. Decisions of the organization or employees and subcommittees of the organization on data release are not reviewable.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

2. General public access; confidentiality. The board shall adopt rules making information provided to the organization under this chapter, except protected health information and other confidential information, available to any person upon request.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

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

A. Release of protected health information must be limited to only information that is necessary for the stated purpose of the release; [PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

B. Data releases must be governed by data use agreements that provide adequate privacy and security measures that include appropriate accountability and notification requirements as required

of business associate agreements under HIPAA; [PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

C. Follow-up must be provided to ensure data are used as specified and that no protected health information is publicly revealed. The board shall adopt rules providing for any necessary data suppression; and [PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

D. Release of more protected health information than a limited data set as described in 45 Code of Federal Regulations, Section 164.514(e) must be approved by the board consistent with state and federal laws. [PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

4. Certain practitioners. The board shall adopt rules to protect the identity of certain health care practitioners, as it determines appropriate, except that the identity of practitioners performing abortions as defined in section 1596 must be designated as confidential and may not be disclosed.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

5. Notice and comment period. The board shall adopt rules to establish criteria for determining whether information is confidential clinical data, confidential financial data or other protected health information and specify procedures to give affected health care practitioners and payors notice and opportunity to comment in response to requests for information that may be considered confidential.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

6. Identifying information. The board shall adopt rules to provide that individuals may be directly or indirectly identified, including through a linking or reidentification process, only as provided in this chapter and the rules of the board. Any protected health information may be used only for the purposes for which the organization releases it.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

7. Minimum use. The board shall adopt rules to provide that persons gaining access to protected health information may use that information to the minimum extent necessary to accomplish the purposes for which approval was granted and for no other purpose.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

8. Limitation on release. The board may not grant approval for release of data if the board finds that the proposed identification of or contact with individuals would violate any state or federal law or diminish the confidentiality of health care information or the public's confidence in the protection of that information in a manner that outweighs the expected benefit to the public of the proposed investigation.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

9. Release; publication and use of data. The board shall adopt rules to govern the release, publication and use of analyses, reports and compilations derived from the health data made available by the organization. The rules must apply to all data collected, stored and released by the organization, including reports under section 8712.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

10. Other privacy protections. Individually identifiable data submitted to the organization that would be protected by Title 5, sections 19203 and 19203-D, Title 34-B, section 1207 or 42 United States Code, Section 290dd-2 may not be linked or reidentified in any way that identifies an individual or in any way for which there is a reasonable basis to believe the information could be used to identify an individual. The board shall adopt rules to ensure privacy and security protections of the data that are at least equivalent to the privacy and security requirements of HIPAA.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

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

[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

12. Oversight and notification to individuals. Rules developed pursuant to this section must include a definition of "breach" and a procedure for notification to affected individuals that is equivalent to those of HIPAA. If a breach requiring notification to affected individuals has occurred, the board shall notify the joint standing committee of the Legislature having jurisdiction over health and human services matters within 30 days of the breach. Information provided pursuant to this subsection must maintain the confidentiality of all individuals affected by the breach.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

13. Individual complaints. The board shall adopt rules to establish a process for an individual to file a complaint if the individual believes that the individual's protected health information has been released by the organization, the board or an employee of the organization, in violation of the board's rules.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

14. Rulemaking. The board shall adopt rules as necessary to implement this section. Rules adopted pursuant to this section are major substantive rules as described in Title 5, chapter 375, subchapter 2-A.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

SECTION HISTORY

PL 2013, c. 528, §10 (NEW). PL 2013, c. 528, §12 (AFF).

§8715. Public health

(CONTAINS TEXT WITH VARYING EFFECTIVE DATES)

(WHOLE SECTION TEXT EFFECTIVE ON CONTINGENCY: See PL 2013, c. 528, §12)

1. Permitted use and disclosure to public health authorities. The organization may disclose protected health information, without an individual's authorization, to a public health authority for public health purposes mandated by state or federal law.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

2. Use by public health authority. A state or federal public health authority to which protected health information has been disclosed under subsection 1 may use that information for public health activities and may disclose that information for public health activities as allowed by state or federal law and in accordance with board rules on data release adopted pursuant to section 8714.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

3. Data use agreement. Prior to disclosing any data under subsection 1, the organization shall enter into a data use agreement with a public health authority. The agreement must include protocols that have been approved by the board for safeguarding confidential information and for ensuring there will be no disclosures of protected health information. The protocols must include appropriate accountability and notification requirements as in the business associate agreements under HIPAA.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

SECTION HISTORY

PL 2013, c. 528, §10 (NEW). PL 2013, c. 528, §12 (AFF).

§8715-A. Reporting of cancer data and vital statistics data

1. Reporting; joint rule-making authority. The organization and the Department of Health and Human Services may adopt a joint rule to require the reporting to the organization of data from the cancer-incidence registry established pursuant to section 1404 and data related to the registration of vital statistics pursuant to section 2701. The rule adopted pursuant to this section is a routine technical rule as described in Title 5, chapter 375, subchapter 2-A.

[PL 2021, c. 423, Pt. A, §9 (NEW).]

2. Confidentiality of data reported. Data reported to the organization in accordance with subsection 1 is the organization's data and must be protected by privacy and security measures consistent with health care industry standards. The data is confidential and may be released only in accordance with the organization's rule on release of data to the public adopted pursuant to section 8707. Any such cancer data or vital statistics data may be released only in accordance with the organization's rule adopted after the effective date of this subsection.
[PL 2021, c. 423, Pt. A, §9 (NEW).]

SECTION HISTORY

PL 2021, c. 423, Pt. A, §9 (NEW).

§8716. Health care improvement studies

(CONTAINS TEXT WITH VARYING EFFECTIVE DATES)

(WHOLE SECTION TEXT EFFECTIVE ON CONTINGENCY: See PL 2013, c. 528, §12)

The board may approve the disclosure of protected health information to persons conducting health care improvement studies, subject to the following conditions. [PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

1. Disclosure to study entities. For health care improvement studies, regarding health care utilization, improvement, cost or quality and involving patients with whom the study entity has a treatment or payor relationship, whether the study is funded by the Federal Government or the State Government or private persons, the organization may disclose protected health information to a study entity who is a covered entity or to the covered entity's business associates if those persons conducting the study do not disclose protected health information to any person not directly involved in the study without consent from the subject of the protected health information.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

2. Recipients of information. A person receiving protected health information under subsection 1 may use that information only to the minimum extent necessary to accomplish the purposes of the study for which approval was granted and for no other purpose.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

3. Confidentiality; protocol. The protocol for any study entity receiving protected health information under subsection 1 must be designed to preserve the confidentiality of all health care information that can be associated with identified patients, to specify the manner in which contact is made with patients and to maintain public confidence in the protection of confidential information.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

4. Additional protection. The board may not grant approval to a study entity under this section for the disclosure of protected health information if the board finds that the proposed identification of or contact with patients would violate any state or federal law or diminish the confidentiality of health care information or the public's confidence in the protection of that information in a manner that outweighs the expected benefit to the public of the proposed investigation.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

5. Data use agreement. Prior to disclosing any data pursuant to subsection 1, the organization shall enter into a data use agreement with a study entity. The agreement must include protocols that have been approved by the board for safeguarding confidential information and for ensuring there will be no disclosures of protected health information. The protocols must include appropriate accountability and notification requirements as in business associate agreements under HIPAA.
[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

SECTION HISTORY

PL 2013, c. 528, §10 (NEW). PL 2013, c. 528, §12 (AFF).

§8717. Covered entities' access to protected health information

(CONTAINS TEXT WITH VARYING EFFECTIVE DATES)

(WHOLE SECTION TEXT EFFECTIVE ON CONTINGENCY: See PL 2013, c. 528, §12)

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

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

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

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

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

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

(5) Business planning, development, management and administration; and

(6) Business management and general administrative activities of the covered entity, including but not limited to de-identifying protected health information, creating a limited data set and permissible fund-raising for the benefit of the covered entity; [PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

B. "Payment activities" means activities of a health plan to obtain premiums, determine or fulfill responsibilities for coverage and provision of benefits and furnish or obtain reimbursement for health care delivered to an individual and activities of a health care provider to obtain payment or be reimbursed for the provision of health care to an individual; and [PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

C. "Treatment" means the provision, coordination or management of health care and related services for an individual by one or more health care providers, including consultation between providers regarding an individual and referral of an individual by one provider to another. [PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

2. Minimum necessary. The board shall develop policies and procedures that reasonably limit disclosures of, and requests for, protected health information for payment activities and health care operations to the minimum extent necessary.

[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

3. Choice regarding disclosure of information. Before approving the release of any protected health information under this chapter, the organization shall implement a mechanism that allows an individual to choose to not allow the organization to disclose and use the individual's health information under this chapter.

[PL 2013, c. 528, §10 (NEW); PL 2013, c. 528, §12 (AFF).]

SECTION HISTORY

PL 2013, c. 528, §10 (NEW). PL 2013, c. 528, §12 (AFF).

§8718. Maine Health Data Organization Health Information Advisory Committee

The Maine Health Data Organization Health Information Advisory Committee, referred to in this section as "the advisory committee," is established in accordance with this section to make recommendations to the organization regarding public reporting of health care trends developed from data reported to the organization pursuant to this chapter. [PL 2021, c. 423, Pt. A, §10 (NEW).]

1. Membership. The advisory committee consists of the following 11 members:

A. The executive director of the organization; [PL 2021, c. 423, Pt. A, §10 (NEW).]

B. One member of the Senate, appointed by the President of the Senate; [PL 2021, c. 423, Pt. A, §10 (NEW).]

C. One member of the House of Representatives, appointed by the Speaker of the House of Representatives; [PL 2021, c. 423, Pt. A, §10 (NEW).]

D. The commissioner or the commissioner's designee; [PL 2021, c. 423, Pt. A, §10 (NEW).]

E. The Superintendent of Insurance or the superintendent's designee; and [PL 2021, c. 423, Pt. A, §10 (NEW).]

F. Six members appointed by the board as follows:

(1) One member representing consumers of health care;

(2) One member representing providers;

(3) One member representing hospitals;

(4) One member representing employers;

(5) One member representing carriers; and

(6) One member representing the state employee health plan under Title 5, section 285. [PL 2021, c. 423, Pt. A, §10 (NEW).]

[PL 2021, c. 423, Pt. A, §10 (NEW).]

2. Duties. The advisory committee shall:

A. Make recommendations to the organization to establish priorities for health care trend data items; [PL 2021, c. 423, Pt. A, §10 (NEW).]

B. Make recommendations to the organization on the annual public reporting of health care trend data items pursuant to this chapter; and [PL 2021, c. 423, Pt. A, §10 (NEW).]

C. Make additional health care data trend-related recommendations as requested by the executive director of the organization. [PL 2021, c. 423, Pt. A, §10 (NEW).]

[PL 2021, c. 423, Pt. A, §10 (NEW).]

3. Terms. Except for Legislators, members of the advisory committee appointed by the board serve 5-year terms except for initial appointments. Initial appointments must include one member appointed to a 3-year term, 2 members appointed to 4-year terms and 3 members appointed to 5-year terms. A member may not serve more than 2 consecutive terms. The terms of Legislators serving as members of the advisory committee coincide with their legislative term of office.
[PL 2021, c. 423, Pt. A, §10 (NEW).]

4. Compensation. Except for Legislators, members of the advisory committee are eligible for compensation according to the provisions of Title 5, chapter 379.
[PL 2021, c. 423, Pt. A, §10 (NEW).]

5. Quorum. A quorum is a majority of the members of the advisory committee.

[PL 2021, c. 423, Pt. A, §10 (NEW).]

6. Chair and officers. The advisory committee shall annually choose one of its members to serve as chair for a one-year term. The advisory committee may select other officers and designate their duties.
[PL 2021, c. 423, Pt. A, §10 (NEW).]

7. Meetings. The advisory committee shall meet at least 4 times a year at regular intervals and may meet at other times at the call of the chair or the executive director of the organization. Meetings of the advisory committee are public proceedings as provided by Title 1, chapter 13, subchapter 1.
[PL 2021, c. 423, Pt. A, §10 (NEW).]

SECTION HISTORY

PL 2021, c. 423, Pt. A, §10 (NEW).

§8719. Provider database and service locator tool

1. Provider database. The organization shall develop and maintain a multipayor provider database that must be used by the department to provide information for a service locator available on a publicly accessible website for use by the public, by providers and by state agencies in accordance with this section. The organization and the department shall leverage existing data sources to maintain the database whenever possible, as allowable by state and federal law. Creation and maintenance of the database may not increase mandatory reporting requirements for providers of physical health services, and reporting requirements for providers of behavioral health services must be kept to the minimum necessary to ensure development of a useful database and tool for analytic, consumer service and provider identification and referral purposes. The organization shall collaborate with the department as necessary on the development and maintenance of the database.
[PL 2021, c. 423, Pt. B, §3 (NEW).]

2. Funding. The development of the multipayor provider database and service locator tool under subsection 1 must be funded using existing resources within the department and grant funding obtained by the department from public and private sources. The organization and the Office of MaineCare Services within the department are jointly responsible for the ongoing maintenance costs of the provider database using existing resources.
[PL 2021, c. 423, Pt. B, §3 (NEW).]

SECTION HISTORY

PL 2021, c. 423, Pt. B, §3 (NEW).

SUBCHAPTER 3

PRESCRIPTION DRUG PRICING FOR PURCHASERS

§8731. Definitions

As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings. [PL 2019, c. 470, §8 (NEW).]

1. Brand-name drug. "Brand-name drug" means a prescription drug marketed under a proprietary name or registered trademark name, including a biological product.
[PL 2019, c. 470, §8 (NEW).]

1-A. Drug product family. "Drug product family" means a group of one or more prescription drugs that share a unique generic drug description and drug form.
[PL 2021, c. 305, §1 (NEW).]

1-B. Category of insulin. "Category of insulin" means rapid-acting, short-acting, intermediate-acting, long-acting and premixed insulin for which at least 2 licenses have been issued by the federal Food and Drug Administration and are actively marketed pursuant to such licensure in a category.
[PL 2023, c. 610, §1 (NEW).]

2. Generic drug. "Generic drug" means a prescription drug, whether identified by its chemical, proprietary or nonproprietary name, that is not a brand-name drug and is therapeutically equivalent to a brand-name drug in dosage, safety, strength, method of consumption, quality, performance and intended use. "Generic drug" includes a biosimilar product.
[PL 2019, c. 470, §8 (NEW).]

2-A. Insulin. "Insulin" has the same meaning as in Title 32, section 13786-D, subsection 1, paragraph A and includes insulin or an insulin pen that is licensed under the federal Public Health Service Act, 42 United States Code, Section 262(a) or 262(k).
[PL 2023, c. 610, §2 (NEW).]

3. Manufacturer. "Manufacturer" means an entity that manufactures or repackages, and sets the wholesale acquisition cost for, prescription drugs that are distributed in the State.
[PL 2021, c. 305, §2 (AMD).]

3-A. Prescription drug. "Prescription drug" means a drug, as defined in 21 United States Code, Section 321(g) or a biological product as defined in 42 United States Code, Section 262(i)(1) that:

A. Is intended for human use; [PL 2021, c. 305, §3 (NEW).]

B. Is not a device within the meaning of 21 United States Code, Section 321(h); and [PL 2021, c. 305, §3 (NEW).]

C. By federal or state law, can be lawfully dispensed or administered only on prescription by a licensed health care professional. [PL 2021, c. 305, §3 (NEW).]
[PL 2021, c. 305, §3 (NEW).]

4. Pricing component data. "Pricing component data" means data unique to each manufacturer, wholesale drug distributor or pharmacy benefits manager subject to this subchapter that evidences the cost to each manufacturer, wholesale drug distributor or pharmacy benefits manager to make a prescription drug available to consumers and the payments received by each manufacturer, wholesale drug distributor or pharmacy benefits manager to make a prescription drug available to consumers, taking into account any price concessions, and that is measured uniformly among the entities, as determined by rules adopted by the organization pursuant to section 8737.
[PL 2019, c. 470, §8 (NEW).]

5. Pricing unit. "Pricing unit" means the smallest dispensable amount of a prescription drug that could be dispensed.
[PL 2019, c. 470, §8 (NEW).]

6. Wholesale acquisition cost. "Wholesale acquisition cost" means a manufacturer's listed price for sale to a wholesale drug distributor or other entity that purchases a prescription drug directly from the manufacturer, not including any price concessions.
[PL 2019, c. 470, §8 (NEW).]

SECTION HISTORY

PL 2019, c. 470, §8 (NEW). PL 2021, c. 305, §§1-3 (AMD). PL 2023, c. 610, §§1, 2 (AMD).

§8732. Drug price notifications and disclosures

1. Notifications by manufacturers.

[PL 2021, c. 305, §4 (AMD); MRSA T. 22 §8732, sub-§1 (RP).]

1-A. Public notice of substantial drug price change or introduction. No later than January 30, 2022 and annually thereafter, the organization shall produce and post on its publicly accessible website a list of prescription drugs for which the manufacturer has during the prior calendar year:

A. Increased the wholesale acquisition cost of a brand-name drug by more than 20% per pricing unit; [PL 2021, c. 305, §5 (NEW).]

B. Increased the wholesale acquisition cost of a generic drug that costs at least $10 per pricing unit by more than 20% per pricing unit; or [PL 2021, c. 305, §5 (NEW).]

C. Introduced a new drug for distribution in this State when the wholesale acquisition cost is greater than the amount that would cause the drug to be considered a specialty drug under the Medicare Part D program. For the purposes of this paragraph, "Medicare Part D" has the same meaning as in section 254-D, subsection 1, paragraph F. [PL 2021, c. 305, §5 (NEW).]

[PL 2021, c. 305, §5 (NEW).]

2. Disclosures by manufacturers, wholesale drug distributors and pharmacy benefits managers. The following disclosures apply to manufacturers, wholesale drug distributors and pharmacy benefits managers.

A. On or before February 15th of each year, the organization shall produce and post on its publicly accessible website a list of drug product families for which it intends to request pricing component data from manufacturers, wholesale drug distributors and pharmacy benefits managers. The organization shall base its inclusion of drug product families on any information the organization determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the State, and the organization shall consider drug product families that include prescription drugs:

(1) Included in the public notice of substantial drug price change or introduction under subsection 1-A; and

(2) For which the organization is required to produce an annual report pursuant to section 8712, subsection 5, including, but not limited to, the 25 costliest drugs, the 25 most frequently prescribed drugs in the State and the 25 drugs with the highest year-over-year cost increases. [PL 2021, c. 305, §6 (NEW).]

B. Not sooner than 30 days after publicly posting the list of drug product families pursuant to paragraph A, the organization shall notify, via e-mail, manufacturers, wholesale drug distributors and pharmacy benefits managers pursuant to paragraph C. [PL 2021, c. 305, §6 (NEW).]

C. Within 60 days from the date of a request from the organization relating to a specific prescription drug, a manufacturer, wholesale drug distributor or pharmacy benefits manager shall notify the organization of pricing component data per pricing unit of the prescription drug. [PL 2021, c. 305, §6 (NEW).]

[PL 2021, c. 305, §6 (RPR).]

3. Notification by manufacturers of wholesale acquisition cost for insulin. No later than February 15th of each year, a manufacturer of insulin shall notify the organization of the wholesale acquisition cost per pricing unit for the insulin produced by the manufacturer in each category of insulin. [PL 2023, c. 610, §3 (NEW).]

SECTION HISTORY

PL 2019, c. 470, §8 (NEW). PL 2021, c. 305, §§4-6 (AMD). PL 2023, c. 610, §3 (AMD).

§8733. Confidentiality

Information provided to the organization as required by this subchapter by a manufacturer, wholesale drug distributor or pharmacy benefits manager is confidential and not a public record under Title 1, chapter 13, except that the organization may share information: [PL 2019, c. 470, §8 (NEW).]

1. Bureau of Insurance. With the Department of Professional and Financial Regulation, Bureau of Insurance, to the extent necessary for the bureau to enforce the provisions of Title 24-A, as long as any information shared is kept confidential;
[PL 2021, c. 305, §7 (AMD).]

2. Aggregate. In the aggregate, as long as it is not released in a manner that allows the determination of individual prescription drug pricing contract terms covering a manufacturer, wholesale drug distributor or pharmacy benefits manager; and
[PL 2021, c. 305, §7 (AMD).]

3. Publicly available. That is available, for purchase or otherwise, to the public.
[PL 2021, c. 305, §7 (NEW).]

SECTION HISTORY

PL 2019, c. 470, §8 (NEW). PL 2021, c. 305, §7 (AMD).

§8734. Registration requirements

Beginning January 1, 2020, manufacturers, wholesale drug distributors and pharmacy benefits managers subject to this subchapter shall register annually with the organization in a manner prescribed by the organization. [PL 2021, c. 305, §8 (AMD).]

SECTION HISTORY

PL 2019, c. 470, §8 (NEW). PL 2021, c. 305, §8 (AMD).

§8735. Compliance

1. Certification of accuracy. A manufacturer, wholesale drug distributor or pharmacy benefits manager that submits a notification or report to the organization pursuant to this subchapter shall submit with the notification or report a signed written certification of the notification's or report's accuracy.
[PL 2019, c. 470, §8 (NEW).]

2. Civil penalty. A manufacturer, wholesale drug distributor or pharmacy benefits manager that violates this subchapter commits a civil violation for which a fine of $30,000 may be adjudged for each day of the violation.
[PL 2019, c. 470, §8 (NEW).]

3. Audit. The organization may audit the data submitted by a manufacturer, wholesale drug distributor or pharmacy benefits manager pursuant to this subchapter. The manufacturer, wholesale drug distributor or pharmacy benefits manager shall pay for the costs of the audit.
[PL 2019, c. 470, §8 (NEW).]

4. Corrective action plan. The organization may require a manufacturer, wholesale drug distributor or pharmacy benefits manager subject to this subchapter to develop a corrective action plan to correct any deficiencies the organization finds with the manufacturer's, wholesale drug distributor's or pharmacy benefits manager's compliance with this subchapter.
[PL 2019, c. 470, §8 (NEW).]

SECTION HISTORY

PL 2019, c. 470, §8 (NEW).

§8736. Public report

Beginning November 1, 2020 and annually thereafter, the organization shall produce and post on its publicly accessible website an annual report, including information developed from the disclosures

received pursuant to this subchapter on trends in the cost of prescription drugs, analysis of manufacturer prices and price increases, the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and cost sharing and any other information the organization determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the State. The report may not make public any information that is confidential pursuant to section 8733. The organization shall submit the report required by this section to the joint standing committee of the Legislature having jurisdiction over health data reporting and prescription drug matters and the committee may report out legislation to the first regular or second regular session of the Legislature, depending on the year in which the report is submitted. [PL 2021, c. 305, §9 (AMD).]

SECTION HISTORY

PL 2019, c. 470, §8 (NEW). PL 2021, c. 305, §9 (AMD).

§8737. Rulemaking

The organization may adopt rules to implement this subchapter. Rules adopted pursuant to this section are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A. [PL 2019, c. 470, §8 (NEW).]

SECTION HISTORY

PL 2019, c. 470, §8 (NEW).

SUBCHAPTER 4

INTERNATIONAL REFERENCED RATE PRICING FOR PRESCRIPTION DRUGS

§8741. International referenced rate pricing

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Manufacturer" has the same meaning as in section 8731, subsection 3. [PL 2021, c. 606, §1 (NEW).]

B. "Prescription drug" has the same meaning as in section 8731, subsection 3-A. [PL 2021, c. 606, §1 (NEW).]

C. "Referenced rate" means the maximum rate established using the wholesale acquisition cost and other pricing data described in subsection 2, paragraph B. [PL 2021, c. 606, §1 (NEW).]

D. "Wholesale acquisition cost" has the same meaning as in section 8731, subsection 6. [PL 2021, c. 606, §1 (NEW).]

[PL 2021, c. 606, §1 (NEW).]

2. Referenced rates determined. The following provisions govern the determination of referenced rates of prescription drugs.

A. Based on the payments reported in the organization's claims database, the organization shall identify the 100 most costly prescription drugs and the 100 most frequently prescribed prescription drugs in the State, the manufacturers of those drugs and the average wholesale acquisition cost for each drug for the most current 12-month period. [PL 2021, c. 606, §1 (NEW).]

B. To the extent possible, the organization, in conjunction with the Maine Prescription Drug Affordability Board established in Title 5, section 12004-G, subsection 14-I, shall determine the referenced rate for each drug identified in paragraph A by comparing the wholesale acquisition cost to the cost in official publications of the governments of the Canadian provinces of Ontario,

Quebec, British Columbia and Alberta. The referenced rate for each prescription drug must be calculated as the lowest cost among the resources described in this paragraph and the wholesale acquisition cost for the most recent 12-month period. If a specific drug identified in paragraph A is not included within the resources described in this paragraph, the organization shall use for the purpose of determining the referenced rate the ceiling price for drugs as reported in other official publications of the government of Canada. [PL 2021, c. 606, §1 (NEW).]

C. For each drug identified in paragraph A, the organization shall determine the potential savings that could be achieved by subjecting those drugs to the referenced rate as calculated pursuant to paragraph B. The savings must be determined based on the payments reported in the organization's claims database for the most current 12-month period. [PL 2021, c. 606, §1 (NEW).]

[PL 2021, c. 606, §1 (NEW).]

3. Reporting. By January 1, 2023, and annually thereafter, the organization shall produce and post on its publicly accessible website a report including the information required under subsection 2. The organization shall submit the report required by this subsection to the Office of Affordable Health Care established in Title 5, section 3122, the Maine Prescription Drug Affordability Board established in Title 5, section 12004-G, subsection 14-I and the joint standing committee of the Legislature having jurisdiction over health data reporting and prescription drug matters. The joint standing committee of the Legislature having jurisdiction over health data reporting and prescription drug matters may report out legislation based on the report to the first regular or second regular session of the Legislature, depending on the year in which the report is submitted.

[PL 2021, c. 606, §1 (NEW).]

SECTION HISTORY

PL 2021, c. 606, §1 (NEW).