90-590 MAINE HEALTH DATA ORGANIZATION

Chapter 120: RELEASE OF DATA TO THE PUBLIC

SUMMARY: This chapter provides for the manner and extent to which data submitted to or assembled by the MHDO or its predecessor agencies will be made available to the public. The rule defines the scope of the exceptions to the Freedom of Access Law that is provided in the Maine Health Data Organization statute. The rule also establishes procedures for determining whether data are confidential or privileged and for protecting filed data until that decision is made.

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1. Applicability

This rule governs disclosure to the public of data in the possession of the Maine Health Data Organization or its designee. Only data that are physically recorded or stored in written, printed, graphic, or electronic form, as opposed to the individual knowledge of Board or staff members, are covered by this rule. The coverage of all such data in this rule shall not be construed as an MHDO determination that all recorded or stored data within its offices or those of its designee are "public records" within the meaning of 1 M.R.S.A. Sec. 402(3) (1996).

2. Definitions

A. **Carrier**. "Carrier" means an insurance company licensed in accordance with 24-A M.RS.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 24 M.R.S.A. An employer exempted from the applicability of 24-A M.R.S.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.

B. **Clinical Data**. “Clinical data” mean health care claims, hospital, non-hospital health care facility data, quality data, and all other data as described in 22 M.R.S.A. Secs. 8708, 8708-A, and 8711.

C. **Confidential Data**. "Confidential data" mean "Confidential Restructuring Data," "Confidential Agency Data", "Confidential Clinical Data,” or “Confidential Financial Data," as defined below:

1. "Confidential Restructuring Data" mean any information filed by a data provider in connection with its corporate plan or reorganization that contains either a trade secret or contract information:

(a) that have not yet been revealed to persons other than:

(i) employees, agents, or attorneys of the data provider;

(ii) other persons or entities with which the data provider is engaged in a joint venture or other commercial action in concert;

(iii) other persons or entities with which the data provider is actively negotiating for the purchase or sale of goods or services;

(iv) other persons or entities with which the data provider is jointly participating in an effort to obtain financing; and

(v) other persons or entities to which the data provider has applied for financing;

(b) that would, if revealed, substantially and adversely affect the ability of the data provider, its affiliated interests or the other persons or entities with which the data provider is engaging in a joint venture or commercial action to compete with other entities offering or proposing to offer the same goods and services in the same market; or, that would, if revealed, substantially and adversely affect the ability of the data provider or its affiliated interest to obtain financing on reasonable terms in competition with others seeking similar types of capital; or

(c) that could lawfully be concealed under applicable laws governing financial transactions.

2. "Confidential Agency Data" are data collected or produced by the MHDO that:

(a) have not been revealed to the general public;

(b) can be withheld from public access without violation of the Freedom of Access Law, 1 M.R.S.A. Sec. 400 *et seq*.; and

(c) should not, in the opinion of the Executive Director, be released.

3. "Confidential Clinical Data" or “Confidential Financial Data” are data provided to the MHDO that:

(a) have not been revealed to the general public; and

(b) will directly result in the data provider being placed in a competitive economic disadvantage.

D. **Data Provider**. A “data provider” provides data to the MHDO pursuant to 22 M.R.S.A. Secs. 8708, 8708-A, 8709, 8710 or 8711 and is a health care facility, health care practitioner, or health care claims processor.

E. **Disclosure**. "Disclosure," with respect to clinical, financial, or restructuring data, means to communicate information to a person not already in possession of that information or to use information for a purpose not originally authorized. For example, to inform a person of the identity of a previously unnamed patient is to "disclose" clinical data not already in that person's possession with respect to the patient.

F. **Executive Director**. “Executive Director” means the Executive Director of the MHDO or his/her successors.

G. **Financial Data**. “Financial data” means information collected from data providers pursuant to Chapter 300 of the MHDO rules, *Uniform Reporting System for Hospital Financial Data*, that include, but are not limited to, costs of operation, revenues, assets, liabilities, fund balances, other income, rates, charges and units of services.

H. **Health Care Claims Data**. “Health care claims data” means information consisting of or derived directly from member eligibility, medical claims, pharmacy claims, and/or dental claims files submitted by health care claims processors pursuant to Chapter 243 of the MHDO’s rules, *Uniform Reporting System for Health Care Claims Data Sets*. “Health care claims data” do not include analysis, reports, or studies containing information from health care claims data sets, if those analyses, reports, or studies have already been released in response to another request for information or as part of a general distribution of public information by the MHDO.

I. **Health Care Claims Processor**. “Health care claims processor” means a third-party payer, third-party administrator, Medicare health plan sponsor, or pharmacy benefits manager.

J. **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 22 M.R.S.A., chapter 160, a health care facility licensed under 22 M.R.S.A., chapter 405 or certified, 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 a 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 22 M.R.S.A., chapter 419, a residential care facility licensed under 22 M.R.S.A., chapter 1663, a hospice provider licensed under 22 M.R.S.A., chapter 1681, a retail store drug outlet licensed under 32 M.R.S.A., chapter 117, a state institution as defined under 34-B M.R.S.A., chapter 1 and a mental health facility licensed under 34-B M.R.S.A., chapter 1.

K. **Health Care Practitioner**. "Health care practitioner" means physicians and all others certified, registered or licensed in the healing arts, including but not limited to, nurses, podiatrists, optometrists, pharmacists, chiropractors, physical therapists, dentists, psychologists and physicians’ assistants as defined in 24 M.R.S.A., chapter 21. "Health care practitioner" also includes licensed clinical social workers as defined in 32 M.R.S.A., chapter 83 and marriage and family therapists and professional counselors as defined in 32 M.R.S.A., chapter 119.

L. **Hospital Data**. "Hospital data" means information consisting of or derived directly from hospital inpatient, outpatient, emergency department, or any other derived data sets filed or maintained pursuant to Chapter 241 of the MHDO’s rules, *Uniform Reporting System for Hospital Inpatient and Hospital Outpatient Data Sets*. "Hospital data" do not include analysis, reports, or studies containing information from hospital data sets, if those analyses, reports, or studies have already been released in response to another request for information or as part of a general distribution of public information by the MHDO.

L-1. **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.

M. **MHDO**. “MHDO” means the Maine Health Data Organization or its predecessor agencies.

N. **MHDO Records**.

1. "MHDO record" means any item of data stored in written, printed, graphic, or electronic form that is either:

(a) contained within the official agency record of an MHDO rulemaking proceeding;

(b) filed with the MHDO or its designee by a data provider in accordance with a requirement of statute, rule or MHDO order;

(c) contained in the minutes of MHDO meetings; or

(d) contained in a final MHDO report, analysis, study, data compilation, decision, rule, or order;

2. "MHDO record" does not include any of the following:

(a) the contents of files maintained by the MHDO's lawyers, or any material prepared in anticipation of litigation;

(b) draft documents of any kind, including unsigned or incomplete memoranda, decisions, rules or other papers; nor

(c) reports studies, analyses, or data compilations that have not yet been reviewed for public release pursuant to section 9 or 10.

O. **M.R.S.A.** “M.R.S.A.” means Maine Revised Statutes Annotated.

P. **Non-Hospital Health Care Facility Data**. “Non-hospital health care facility data” means information or data consisting of or derived directly from data sets filed or maintained pursuant to Chapter 245 of the MHDO’s rules, *Uniform Reporting System for Non-Hospital Ambulatory Service Data Sets*. “Non-hospital health care facility data” do not include analysis, reports, or studies containing information from non-hospital health care facility data sets, if those analyses, reports, or studies have already been released in response to another request for information or as part of a general distribution of public information by the MHDO.

P-1. **Pharmacy Benefits Manager**. "Pharmacy benefits manager" means an entity that performs pharmacy benefits management as defined by 22 M.R.S.A., § 2699.

Q. **Plan Sponsor**. “Plan sponsor” means any person, other than an insurer, who establishes or maintains a plan covering residents of the State of Maine, including, but not limited to, plans established or maintained by two 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.

Q-1. **Prescriber Data**. "Prescriber data" means information or data collected from data providers pursuant to Chapter 280 of the MHDO's rules, *Filing Requirements for Prescribers Seeking Confidentiality Requirements*, that include, but are not limited to, prescriber names, addresses, Maine license or certificate numbers, Drug Enforcement Authority registration numbers, and National Provider Identification numbers.

R. **Privileged Medical Information**. "Privileged medical information" means information other than hospital, non-hospital health care facility, or health care claims data that identify individual patients and that are derived from communications that:

1. were made for the purpose of diagnosis or treatment among a provider of health care, persons assisting the provider or patient, and a patient;

2. were made for the purpose of payment of health care services among a provider of health care, a health care claims processor, and a patient;

3. were not intended to be disclosed except to persons necessary to transmit or record the communication and persons participating in the diagnosis, treatment, or payment; and

4. have not been previously disclosed to the general public.

S. **Protected Information**. "Protected information" means information that is subject to a protective order that was issued by a court and is binding on the MHDO or that was issued by the MHDO, either as part of an adjudicatory proceeding or as a general order pursuant to section 12 of this Chapter.

T. **Quality Data**. “Quality data” means information consisting of or derived directly from data providers pursuant to Chapter 270 of the MHDO’s rules, *Uniform Reporting System for Quality Data Sets*. "Quality data" do not include analysis, reports, or studies if those analyses, reports, or studies have already been released as part of a general distribution of public information by the MHDO.

U. **Release**. To "release" data is to make it available for inspection and copying to persons other than the data provider.

V. **Restructuring Data**. “Restructuring data” means information collected from data providers pursuant to Chapter 630 of the MHDO rules, *Uniform System for Reporting Baseline Information and Restructuring Occurrences for Maine Hospitals and Parent Entities*, that include, but are not limited to, organizational structure, location of separate health service delivery sites or treatment centers, acquisitions, consolidations, or mergers.

W. **Staff Delegate**. “Staff delegate” means a member of the MHDO staff to whom the Executive Director delegates specific responsibilities under this Chapter.

X. **Third-Party Administrator**. “Third-party administrator” means any person licensed by the Maine Bureau of Insurance under 24-A M.R.S.A., chapter 18 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.

Y. **Third-Party Payer**. "Third-party payer" means a state agency that pays for health care services or 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 payer” 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.

3. Public Access to Data

A. **MHDO Records Not Otherwise Restricted**. Except as otherwise provided in this section, all MHDO records shall be released to any person, in accordance with sections 4 and 5, below.

B. **Clinical Data**. MHDO records, files, reports, tables or any other information consisting of or compiled from clinical data shall be released, but only after the review and modification procedures set forth in section 9 have been undertaken. Computations, reports, or tables containing clinical data may be released without review, if the data have previously been designated as public.

C. **Financial or Restructuring Data**. MHDO files, reports, tables or any other information consisting of or compiled from financial or restructuring data shall be released in accordance with the provisions set forth in section 10. Computations, reports, or tables containing financial or restructuring data may be released without review, if the data have previously been designated as public.

D. **Data Claimed to be Confidential or Privileged**. Those parts of MHDO records that have been properly claimed to contain confidential data or privileged medical information pursuant to section 6 shall not be released unless the Executive Director or a staff delegate determines, pursuant to section 7 or section 8, that the requested data or medical information are not confidential or privileged.

E. **MHDO Documents Containing Confidential, Privileged, or Protected Data**. MHDO documents labeled in accordance with subsection 11(A), shall not be released, until the confidential, privileged, or protected data have been removed or obliterated.

F. **Data Subject to Protective Order**. Those parts of MHDO records that are subject to a protective order and are properly labeled as protected shall not be released except to the extent that the order may allow.

G. **Information Other than MHDO Records**. Information in the MHDO's possession that does not constitute or form part of a MHDO record may be released after a request made in accordance with section 4, only if the Executive Director or a staff delegate finds that review under subsection 11(C) is not required and either:

1. that the information is a "public record" within the meaning of 1 M.R.S.A. Sec. 402 (3); or

2. that the information is not a "public record" but that its disclosure:

(a) will not infringe upon confidential, privileged, or protected status provided elsewhere in this Chapter; and

(b) will be appropriate and reasonable as determined by the Executive Director or staff delegate.

H. **Prescriber Data**. MHDO files, reports, tables, or any other information consisting of or compiled from prescriber data shall be released, but must not contain any data as identified in section 9(A)(4).

4. Request for Data

A. **Request for Data**. Each request for data shall be in writing and shall state with specificity: the MHDO data or other information sought; the identity, including ownership, of the requesting party; whether or not an internal review board is to be utilized; the purpose(s) for which it will be used; and the media on which the data are to be delivered. If the requesting party intends to display on the Internet any of the data sought, the request for such data must so specify. Any request that does not contain sufficient detail to enable the MHDO's staff to locate the desired data with a reasonable expenditure of time and effort may be rejected without being granted or denied. When clinical data requests contain data elements as set forth in subsections 9(A)(2), (3), and (4) of this Chapter, the request shall also set forth:

1. the ultimate recipient or user of the data;

2. any facts bearing on the willingness and ability of the requesting party and ultimate recipient or user of the data to comply with subsection 9 (B)(2)(b) of this Chapter; and

3. the term during which the research will be conducted or the data will be utilized.

In order to ensure that the standards and conditions set forth in section 9 and 10 are met, the Executive Director or staff delegate may request additional information from the requesting party.

B. **Initial Action on Request**. Upon the filing of a request, the Executive Director or a staff delegate shall determine whether any portions of the information requested must be reviewed under sections 7, 8, 9, or 10 below, or must be modified under subsection 3(E), above. Within thirty business days of the filing of the request, the Executive Director or a staff delegate shall:

1. release to the requesting party pursuant to section 5 all information not subject to review under sections 7, 8, 9, and 10, and not withheld from release pursuant to subsections 3(E), (F), and (G);

2. issue a written denial with respect to any information withheld pursuant to subsections 3(E), (F), or (G); and

3. issue a written, temporary denial with respect to any requested information subject to sections 7, 8, 9, or 10, including an explanation to the requesting party that further steps are required to comply with statutory restrictions on the release of the information or to seek review of an agency determination of confidentiality.

C. **Reconsideration of Initial Action**. Any requesting party who has not been provided an opportunity to be heard on the reasons stated in a written denial may request reconsideration within 5 days of the service of the denial. All facts and arguments in support of the motion shall be recited therein. If the Executive Director determines the written submissions do not provide a sufficient basis for a decision, the Executive Director may convene a hearing pursuant to the Maine Administrative Procedures Act.

5. Release of Information and Data

A. **Inspection and Copying of Existing Documents**. Inspection and copying shall be conducted:

1. at the offices in which the information released is made available; and

2. in a manner that assures that the copied material is not damaged.

The Executive Director or a staff delegate may require that copying be conducted by MHDO staff.

B. **Copying Costs**. Reasonable costs of copying shall be paid by the requesting party. Upon request, MHDO staff shall provide estimates of cost in advance of copying. The estimates shall be based upon the applicable fees listed in Chapter 50 of the MHDO's rules.

C. **Translation, Compilation, Reconfiguration, and Modification**

1. When information must be translated from one medium to another, compiled from several sources, reconfigured, or modified to avoid disclosure of information that must under this Chapter be withheld, the costs of all such operations shall be charged to the requesting party. Such charges must be paid before the requested information is delivered.

2. Notwithstanding the thirty business day period provided in subsection 4(B), when the operations described above in subsection 5(C)(1) are required to fulfill a request, such operations and subsequent inspection may be scheduled to occur at such time as will not delay or inconvenience the regular activities of the MHDO staff.

D. **Notice of Release**

Whenever financial or restructuring data pertaining to a specific data provider are released, the MHDO shall notify the filing party.

6. Claims of Confidentiality or Privilege

A. Responsibility of Data Provider

1. **At Time of Submission**. Whenever a data provider claims that data are confidential or privileged within the meanings established in section 2, it shall clearly label each page (or, in the case of electronically stored data, each subdivision of similar size) to which the claim applies as "Confidential" or "Privileged," before submitting the data to MHDO. Each submission that includes portions labeled as confidential or privileged shall be accompanied by a covering letter or report that sets forth the basis for each claim of confidentiality or privilege.

2. **Subsequent to Submission**. When a data provider discovers or concludes, after the submission of data, that they are confidential or privileged and should have been so labeled, it may submit a request that such data be labeled by the MHDO or that the MHDO substitute a labeled copy of the data for the original submission. Any such request shall be accompanied by a letter or report of the basis for the claim of confidentiality or privilege. If the data provider agrees to assume all costs associated with any processing or other data filing, tabulation, recording, or management activities that must be repeated in order to accomplish, or as a consequence of, the subsequent labeling of data, the MHDO will cause the data designated in the request to be labeled as confidential or privileged, or will substitute labeled duplicates and return the original materials. Thereafter, such subsequently labeled material will be treated in the same manner as data claimed to be confidential or privileged pursuant to subsection 6(A)(1), above. Nothing in the subsection, however, shall require the MHDO to retrieve copies of unlabeled data that have been distributed prior to completion of the process of subsequent labeling set forth in this paragraph. The MHDO shall conduct such labeling activities within such time and in such manner as will not disrupt or delay the completion of its other administrative responsibilities.

B. **MHDO Claims**. Whenever the Executive Director or a staff delegate considers data that is an MHDO record to be confidential agency data, such data shall be labeled in the same manner provided for data providers in subsection 6(A). This section shall not be construed to require the MHDO or the staff to comply with subsection 6(A) with respect to confidential agency information that is not an MHDO record.

C. **Disclosure Prohibited**. No data that are properly claimed to be privileged or confidential as provided in this section shall be released, unless the claim is denied after a review under section 7 or 8.

7. Review of Data Claimed by a Data Provider to be Confidential or Privileged

When a request for data includes material labeled by a data provider under section 6, the procedures set forth in this section shall apply.

A. **Notification**. The data provider or providers that submitted the labeled data shall be notified of the request.

B. **Written Support for Confidential or Privileged Designation**. Within ten (10) days of notification, the data provider(s) may submit written memoranda of all facts and arguments that support the claim that the data requested should be found to be confidential or privileged. Copies of such memoranda shall be served on the requesting party.

NOTE: For purposes of computing this ten-day period, MHDO will consider notification to mean service of the notification, in a manner and with the same effect as service under the Maine Rules of Civil Procedure.

C. **Written Opposition from Requesting Party**. Within ten (10) days of the service of the memoranda provided for in subsection 7(B), any opposing memorandum from the requesting party shall be filed.

D. **Burden of Proof**. In reviews under this section, the burden of proof shall rest on the data provider(s) contending that information should not be released. Therefore, if the submissions under subsection 7(B) fail to establish that the data under review are privileged or confidential, the Executive Director or a staff delegate may issue a decision releasing the data without further hearing, subject to the restriction of subsection 7(G).

E. **Requirements for Hearing**. No hearing will be held under this section unless, after review of the memoranda, the Executive Director determines that the memoranda filed do not provide a sufficient basis for a decision, in which case the Executive Director may convene a hearing pursuant to the Maine Administrative Procedure Act.

F. **Review Period for Release**. A decision on whether to release data shall be made within thirty days (30) of the notification given under subsection 7(A).

G. **Effective Release Date**. No decision to release data that have been labeled under section 6 shall take effect less than five days after service of the decision on the data provider.

H. **Modification of Time Periods**. The time periods provided in this section may be modified in particular instances to accommodate the needs of the requesting party or to assure that decisions under this section do not interfere with the MHDO's performance of its primary statutory duties.

I. **Labeling of Data Deemed to be Public**. Once particular items of data have been found not to be privileged or confidential pursuant to this section, a notation to that effect may be made on the affected documents. Thereafter, such items will be treated for purposes of this Chapter as if they were not labeled confidential or privileged. The necessary notation may be accomplished by labeling such items as "public."

8. Review of Data Claimed to be Confidential Agency Data

When a request for data includes material labeled as confidential agency data by the Executive Director or a staff delegate under subsection 6 (B), the procedures set forth in this section shall apply.

A. **Notification**. The requesting party shall be notified that portions of its request are claimed to be confidential by the MHDO, and of the basis for that claim.

B. **Written Support**. The requesting party may submit written memoranda of all facts and arguments that support the claim that the data requested should not be treated as confidential, within five days of the notification given pursuant to subsection (A).

C. **Response to Requesting Party**. If the Executive Director or a staff delegate requests further comment or a response to the requesting party's memoranda from members of the MHDO staff, such comment or response shall be served on the requesting party.

D. **Requirements for Hearing**. No hearing will be held under this section unless, after review of the memoranda, the Executive Director determines that the memoranda filed does not provide a sufficient basis for a decision.

E. **Review Period for Release**. A decision on whether to release information shall be made within twenty (20) days of the notification given under subsection 7(A).

F. **Modification of Time Periods**. The time periods provided in this section may be modified in particular instances to accommodate the needs of the requesting party or to assure that decisions under this section do not interfere with the MHDO's performance of its primary statutory duties.

G. **Labeling of Data Deemed to be Public**. Once particular items of data have been found not to be privileged or confidential pursuant to this section, a notation to that effect may be made on the affected documents. Thereafter, such items will be treated for purposes of this Chapter as if they were not labeled confidential or privileged. The necessary notation may be accomplished by labeling such items as "public."

9. Review of Requests for Clinical Data

Clinical data will be released after they have been reviewed in accordance with this section.

A. The Executive Director or a staff delegate shall compare the clinical data request with the following standards to establish the scope and extent of the request.

1. In accordance with section 3 of Chapter 125 of the MHDO's rules data that directly identify patients, shall not be included in data that are released, unless an exception has been specifically authorized in accordance with subsection 9(D). Data elements that are direct identifiers of individuals under section 3 of Chapter 125 shall be released only in an encrypted form that cannot be used to identify individuals, although it may permit distinctions to be made among unidentifiable individuals. Any data element that is listed under section 3 of Chapter 125 must also be listed in subsection 9(A)(2)(g) to be released in an encrypted format.

2. The following data elements shall be considered to have a possibility of indirectly identifying patients if they show for any individual health record any of the following information and may only be released in accordance with subsection 9(B)(2), unless an exception has been specifically authorized in accordance with section 9(D):

(a) date of birth, unless converted to age;

(b) hospital inpatient admission date or hospital inpatient discharge date, unless each is converted to length of stay plus calendar quarter and year;

(c) hospital inpatient procedure date, unless converted to the number of elapsed days between admission and procedure date;

(d) date of procedure or service, unless converted to calendar quarter and year;

(e) race;

(f) when the place of residence is coded at a level that includes populations of 20,000 persons or less, except to the extent that the MHDO may, by order, approve the use of health planning, regulatory, or research areas containing smaller populations;

(g) medical record number, patient control number, plan specific contract number, member identification code, or patient social security number, in an encrypted form that cannot be used to identify individuals; or

(h) insured group or policy number if the total number of individuals in the group is 50 or greater, or, if less, data associated with other elements listed in this sub-section have been removed prior to release to prevent indirect identification.

3. Data elements related to health care facility or practitioner charges (total charges, line item charges, charge amount) for services rendered shall only be released at an aggregate level that will not allow a charge/paid ratio to be computed for each type of service rendered for any individual health care claims processor, health care facility, or health care practitioner. Requesting parties are prohibited from simultaneously arraying and/or displaying data elements related to payments for specific health care services by individual health care claims processors and health care facilities or practitioners. The MHDO may create public reports or tables arrayed in this manner when all applicable health care facility and practitioner claims for a specific service have been aggregated to produce the total price paid.

4. Any data that directly identifies or would lead to the indirect identification of practitioners performing abortions as defined by 22 M.R.S.A. § 1596, a practitioner's tax identification number, or a practitioner's Drug Enforcement Administration registration number are deemed to be confidential and shall not be released.

B. Release of Clinical Data

1. Upon completion of the review requirements of Section 12, data that meet the standards of subsection 9(A)(1) and contain none of the combinations of data described in subsections 9(A)(2)(3) and (4) shall be released without further review.

2. Except to the extent the data are modified by subsection 9(D), when clinical data meet the standards of subsection 9(A)(1) but contain data elements as described in subsections 9(A)(2), (3), and (4), the following procedure will be employed:

(a) If the Executive Director or a staff delegate finds, on the basis of information received pursuant to section 4:

(i) that the requesting party is seeking the requested clinical data solely for research or statistical purposes;

(ii) that the requesting party is seeking only the clinical data that is necessary to fulfill the specific requirements of the data request;

(iii) that the requesting party has agreed in a writing filed with the MHDO to adhere to the conditions set forth in subsection 9(B)(2)(b); and

(iv) that the requesting party has demonstrated that it can and will faithfully adhere to such conditions and has established procedures to insure such adherence by both it and its employees;

then the MHDO shall initiate the process to release the data that fall within the scope of subsections 9(A)(2), (3), and (4), upon the conditions specified in subsection 9(B)(2)(b). The release of the clinical data shall conform to the external review provisions described in section 12.

(b) Any person to whom clinical data containing elements as set forth in subsections 9(A)(2), (3), and (4) are released shall comply with the conditions in this subsection and shall agree to so comply in writing before receiving any such data.

(i) The data provided will be used by the requesting party and its employees only for research and statistical purposes and only for those purposes specified in the data request, as approved by the MHDO.

(ii) The MHDO shall retain all ownership rights to the data. The requesting party shall have no right, title, or interest to any of the data provided by the MHDO.

(iii) The requesting party shall name an individual as custodian of the data to be responsible for the observance of all conditions of use and for establishment and maintenance of security arrangements to prevent unauthorized use.

(iv) The requesting party shall not release, furnish, disclose, publish or otherwise disseminate the data released to it by the MHDO under this subsection, to any person, except an employee of the requesting party who has agreed in writing to comply with all of the conditions of this paragraph and is subject to such supervision by the requesting party as is necessary to insure such compliance.

Nothing in this subsection, however, shall prevent the requesting party from releasing or disclosing those portions of the data that do not include any of the data elements found in subsections 9(A)(2)(3) and (4).

(v) The requesting party shall make only such additional copies of the data as are required in the conduct of the research and shall retain only one copy of the data after the term of the research as specified in the request, or as modified by the MHDO in approving the request, concludes. All other copies shall be destroyed or returned to the MHDO at the conclusion of the term of the research.

(vi) The requesting party shall not use the data provided in any way, or allow such data to be used in any way, for purposes of identifying individuals or taking legal, administrative or other actions against individuals, nor shall the requesting party make contact with, or assist others in making contact with, any individuals who may be indirectly identified in the data provided.

(vii) The requesting party agrees that the data may be retained only for the period of time necessary to fulfill the requirements of the data request. The requesting party shall return the data within 30 days of the scheduled completion date of the project or shall destroy the data, so certifying by submitting a written notice to the MHDO.

(viii) Except as provided in subsection 9 (B)(2)(b)(ix) the requesting party shall provide the MHDO with a copy of any manuscript, report, or web site universal resource locator (URL) intended for public dissemination that contain data provided under subsection 9(A) at least twenty days prior to their release unless the manuscript, report, or web site is being furnished only to:

a. the requesting party's employees or its other investigators who have agreed with the provisions of this paragraph; or

b. the MHDO.

In the event the MHDO determines that the report may lead to direct or indirect identification of individuals or the determination of a charge/paid ratio, the requesting party shall modify the report prior to its release to protect against such occurrence.

When multiple reports of a similar nature will be created from the data, the MHDO may, in its discretion, upon request, waive the requirement that any subsequent report or reports be provided to the MHDO prior to release by the requesting party. In making such a request, the requesting party shall provide the

MHDO with sufficient information to determine whether the subsequent report(s) will create a risk of direct or indirect identification of individuals or place an individual health care claims processor, health care facility, or health care practitioner at an economic disadvantage.

Reports provided to the MHDO under this subsection shall be considered confidential agency data.

(ix) Subsection 9(B)(2)(b)(viii) shall not apply to a requesting party that:

a. is an agency of the federal or a state government in the United States or the federal or a provincial government in Canada;

b. is subject to a statute, or a rule adopted pursuant to statutory authority, that prohibits the agency from releasing those portions of the data in its custody that would have a possibility of indirectly identifying patients within the meaning of paragraph 9(A)(2); and

c. has responsibility, assigned by statute, for the collection, custody, and release of clinical data.

The exemption established by this subsection shall terminate, and subsection 9(B)(2)(b)(v) shall apply, in the event that the statute or rule described in *b*. immediately above shall be repealed without being replaced by an equivalent provision.

C. **Modification of Data**. When requested clinical data do not meet the standards set forth in subsection 9(A)(1), the MHDO will inform the requesting party. If the requesting party is willing to pay the reasonable cost of modification, the Executive Director or a staff delegate shall modify the requested data to meet the subsection 9(A)(1) standards.

D. **Public Health Exception**. Notwithstanding subsections A (2) and (4) above, the MHDO may release identifying data to the Department of Health and Human Services ("Department") for the purpose of gaining access to medical records and other medical information pertaining to an investigation or research project of substantial public health importance, in accordance with the procedures set forth below.

1. Prior to requesting the release of data under this subsection, the Department will prepare a written protocol, describing the public health investigation or research to be undertaken, including the legal authority under which the investigation or research is being undertaken, the qualifications and affiliations of the staff, the background of the study, the research questions, the research design, case definition and selection, control definition and selection, if any, study resources, study operational description and data analysis methodology.

(a) The protocol must ensure that medical information about patients identified by name is not sought from any person without the consent of that patient, except that, if supported by the specific finding set forth in subsection

9(D)(8)(g), the protocol may provide that information pertaining only to the verification or comparison of health data that the agency is otherwise authorized by law to collect may be obtained without patient consent.

(b) The protocol prepared by the agency shall also describe the procedure for obtaining patient consent to examine medical information, including the manner in which contact will be made with patients and the practices that will be followed to preserve the confidentiality of any medical information that can be associated with an identified patient.

(c) The protocol will be designed to ensure that identifying information released by the MHDO will be used only to gain access to medical records and other medical information for public health purposes identified in the document.

(d) The protocol will be designed to ensure that any identifying information released, with or without consent, shall be subject to all confidentiality requirements established in this section.

2. Each person who seeks access to data released under this subsection must agree in writing to comply with the conditions set forth below before receiving any such data, and thereafter shall comply with the conditions set forth below as well as the conditions set forth in subsections 9 (B)(2)(b)(ii) and 9 (B)(2)(b)(v).

(a) The data released will be used by the Department and its employees only for the specific purposes described in the protocol approved by the MHDO in accordance with this subsection.

(b) Medical information about any patient identified by name shall not be disclosed to any other person, other than another investigator who has agreed to the conditions set forth in this paragraph and is subject to such supervision by the Department as is necessary to ensure compliance with these conditions, without the patient's consent, unless the protocol specifically authorizes verification and comparison without consent in accordance with subsections 9(D)(1)(a) and (8)(g).

(c) Medical information about an identified patient will be used to the minimum extent necessary to accomplish the purposes of the investigation.

(d) The identifying information released will not be used as a basis for legal, administrative, or other actions that may directly affect identified patients as a result of their identification in the investigation, except with the express consent of the identified patient.

(e) Unless specified in the original protocol, no follow back investigations to obtain additional information from patients will be undertaken without obtaining additional authorization under this subsection 9(D).

3. Each protocol prepared in accordance with subsection 9(D)(1) must be submitted to the MHDO with a request for approval of the release of the data required to undertake the proposed study. The request shall be accompanied by written

agreement to all of the conditions set forth in subsection 9(D)(2), signed by each person who will be given access to the released information.

4. After receipt of a request filed pursuant to subsection 9(D)(3), the MHDO shall notify each affected data provider that identifying data has been requested and may be used by the Department for purposes of identifying individual patients. The notice will include a copy of the proposed protocol and will describe the procedures set forth in this subsection and summarize the nature of the proposed investigation or research. Each affected data provider may file written comments within twenty (20) days after service of the notice, with respect to:

   (a) the adequacy of the protection provided to patient confidentiality;

   (b) the purposes for which the information will be used; and

   (c) the extent to which public confidence in the protection of medical information is adequately ensured.

   If necessary to address concerns regarding public confidence in the confidentiality of clinical data, comments from the general public or persons known or expected to be interested in the investigation, research or the requested data may also be sought.

5. The Department submit the protocol prepared in accordance with subsection 9(D)(1) for review and approval by an independent advisory body that has been charged with responsibility for approving the protocol, overseeing the investigation to ensure consistency with the protocol and this Chapter, and assessing the scientific validity of the investigation and its effects upon patients. The composition and organization of the advisory body shall be approved by the MHDO. At a minimum, the advisory body must include two consumer representatives and two health care practitioners in the field related to the investigation or research. The Department may submit the proposed protocol to the advisory body at the same time that it files the protocol and its data request with the MHDO under subsection 9(D)(3), or at any time thereafter.

6. Comments filed with the MHDO in response to the notice issued under subsection 9(D)(4) will be forwarded promptly to the advisory body charged with review of the protocol. The advisory body, after review of the protocol, any comments filed, and any issues or concerns raised by its own members or by the MHDO may recommend revisions of the protocol and may require such revisions as a condition of its approval.

7. If necessary to ensure that the standards and conditions set forth in this subsection will be met, the MHDO may request that additional information or comments be provided by the requesting party and any other persons interested in the proposed investigation, research or the requested data. An informal, oral hearing may be held, if necessary to resolve issues raised by the comments and other information submitted.

8. The MHDO shall authorize the release of identifying data not otherwise permitted under subsection 9(A)(1), and the use of information that may be

released under subsections 9(A)(2) and (4) for the additional purposes specified in this subsection, upon the conditions specified in subsection 9(D)(3), if, upon review of the information received, the MHDO finds the following:

(a) that the protocol required under subsection 9(D)(1) has been prepared, reviewed, and approved by an advisory body in accordance with this subsection and that the protocol conforms with all applicable requirements of this subsection 9(D);

(b) that the proposed identification of or contact with patients does not violate state or federal law nor diminish the confidentiality of medical information;

(c) that the public's confidence in the protection of medical information will not be diminished in a manner that outweighs the expected benefit to the public of the proposed investigation;

(d) that the sole purpose for which information released under this subsection will be used is to obtain medical records and other medical information necessary to the performance of an investigation that is designed to accomplish public health research of substantial public importance where failure to conduct such research may result in serious harm to patients or other individuals;

(e) that the Department and each person who will have access to the data under the auspices of the applicable Maine state agency have agreed in a writing filed with the MHDO to adhere to the conditions set forth in subsection 9(D)(3);

(f) that the Department has demonstrated that it can and will faithfully adhere to the conditions established in this subsection and has in place procedures to ensure such adherence by the agency and its employees; and

(g) that medical information about any patient identified by name will not be sought from any person without consent of that patient, unless:

(i) the information sought pertains solely to verification or comparison of health data that the Department is otherwise authorized by law to collect;

(ii) the manner in which such verification and comparison is carried out is consistent with all applicable requirements of this subsection 9(D); and

(iii) the confidentiality of medical information and the public's confidence in the protection of that information will be adequately protected without patient consent.

10. Review of Requests for Financial or Restructuring Data

Financial or restructuring data shall be released after it has been reviewed in accordance with the provisions of this section.

A. **Review by the MHDO**. The Executive Director or a staff delegate will review the financial or restructuring data request to determine whether it meets the following standards:

1. Confidential financial data, confidential restructuring data, or protected information are not included in the data to be released; and

2. The data to be released shall not in combination with data in the possession of the requesting party result in the data provider being placed in a competitive economic disadvantage.

B. **Release of Financial or Restructuring Data**. Data that meets the provisions of subsection 10(A) shall be prepared for release to the requesting party. The release of the financial or restructuring data shall conform to the external review provisions described in section 12.

11. Review of MHDO Reports and Compilations that May Contain Confidential, Privileged, or Protected Data

A. **All Reports and Compilations**. The Executive Director or a staff delegate shall review every report or data compilation prepared by the MHDO from information in its possession or control, to determine whether any portions of the document contain confidential, privileged, or protected data, or data claimed to fall into those categories. Any such portions will be clearly labeled before the document is deemed final, and the cover of such documents shall state that confidential, privileged, or protected data will be found therein.

B. **Determination of Privilege or Confidentiality**. Should the MHDO or its staff question any claim of confidentiality or privilege with respect to data used in any compilation or report, the Executive Director or a staff delegate may initiate the review process set forth in section 7.

C. **Studies, Analyses, and Reports**. In addition to the review described in subsection 11(A), the MHDO shall provide notification of studies, analyses or reports prepared under 22 M.R.S.A. Sec. 8704(1)(D) to every affected data provider, at least twenty (20) days before such documents are deemed final or made a part of the MHDO's records. Where such documents are to be disseminated to the public, the MHDO's notification shall include:

1. the date that the study, analysis, or report is expected to be made public;

2. the places at which a copy of the study will be available for review on the MHDO web site (http://www.maine.gov/mhdo);

3. the price (not to exceed actual cost of reproducing and mailing the study) and means of obtaining a copy of the study; and

4. the affected data provider's right to file comments on the document with the MHDO before that date. Any such comments that are filed shall be stored by the MHDO with the original or master copy of the study, analysis, or report to which they are directed and shall be released upon request.

12. External Review of Data Recipients/Requests

A. **Data Recipient/Request List**. The MHDO shall create a page on its web site (http://www.maine.gov/mhdo) that lists the identity and address of all parties requesting clinical, financial, restructuring, or prescriber data with a summary of each data request. The MHDO shall update the list on the first business day of every week. In addition, through a written request to the MHDO that must include a valid electronic mail address, a data provider or other interested party shall be automatically notified of any new data requests via electronic mail.

B. **Comments**. Data providers or other interested parties may submit to the Executive Director comments related to the requesting party and/or the proposed use of the data. To be considered, comments must be received by the Executive Director in writing or via electronic mail no later than ten business days after the identity of the requesting party first appears on the MHDO web site. For all data requests that include identifiable practitioner data elements, with the exception of those for prescriber data, or the insured group or policy number, data providers or other interested parties shall have thirty business days to submit comments.

C. **MHDO Determination**. If the Executive Director determines that:

1. The comments are of significant importance to delay the release of the data;

2. Additional information is required from the requesting party to address the comments;

3. The data request includes identifiable practitioner data elements; or

4. The data request includes identifiable group or policy numbers;

then the data shall not be released until the additional information has been received from the requesting party and an additional review is conducted by the MHDO to ensure that the requesting party conforms to all applicable requirements of this chapter. The Executive Director may establish a data advisory committee composed of two members of the MHDO Board, two members of the Maine Health Data Processing Board, and such other individuals, as determined by the Executive Director, with relevant expertise to assist with the additional review of the data request. If the data request includes identifiable practitioner data elements, the Executive Director shall establish a data advisory committee composed of two members of the MHDO Board, two members of the Maine Health Data Processing Board, a representative from the Maine Quality Forum, and representatives from the Maine based practitioner professional associations and/or affiliated medical specialty organizations associated with the potentially impacted practitioners. If the data request includes identifiable group or policy numbers, the Executive Director shall establish a data advisory committee composed of two members of the MHDO Board, two members of the Maine Health Data Processing Center Board, a

representative of an employer or a business organization potentially impacted by the request, a Maine based representative of consumers, a representative of a Maine based third-party payer organization, and a representative of the third party payer potentially impacted by the request. The requirements of this subsection shall not apply to the release of prescriber data.

13. Protective Orders

On its own motion or that of its staff or a data provider, the MHDO may enter a general protective order governing specified items of data. Such an order shall be granted whenever a similar order would be permissible in the course of formal MHDO proceedings or under the Maine Rules of Civil Procedure and Maine Rules of Evidence. Any data that are subject to such an order shall be labeled by the moving party with the words "protected data" or an equally clear indication that it is subject to a protective order. When general protective orders are requested outside of the context of either discovery proceedings or particular requests for data under this rule, the MHDO may issue them *ex parte*, subject to subsequent reconsideration on motion of any party aggrieved thereby.

14. Compliance

A. **False Claims or Labels**. It shall be a violation of this rule to claim and label, in accordance with subsection 6(A), data that do not fall within the scope of the definitions in subsections 2(C), (N) and (R), unless the contention of the data provider that data which fell within these subsections were, although incorrect, substantially justified.

B. **Advanced Protective Order**. Any data provider that violates this rule in the manner described in subsection 14(A) shall be required, in all submissions made with the MHDO for one year following an order finding a violation, to obtain a protective order in advance of the date of submission for any data claimed to be confidential or privileged. All data submitted without such an order shall be released on request. Any motion for such an order shall be made at least thirty days in advance of the required submission date.

C. **Second Offense**. The penalties provided in 22 M.R.S.A Sec. 8705-A shall apply to a second offense under subsection 14(A), and to any other violations of the requirements of this Chapter.

15. Relationship to Discovery

A. **Request for Data**. Inquiries that purport to be requests filed pursuant to this Chapter but actually seek data in the form and character of discovery in a pending proceeding before the MHDO or a court or administrative proceeding to which the MHDO is a party shall not be deemed to be requests for data. Such inquiries will be processed in accordance with the rules of practice applicable to the case to which the discovery would apply.

B. **Confidential, Privileged, or Protected Data**. Nothing in this Chapter shall limit or modify the right of a directly interested person to seek discovery from a data provider of data that may not be released by the MHDO under this Chapter. The MHDO may order

such discovery with any protective restrictions that may appear necessary, pursuant to such rules of practice as the MHDO may adopt.

16. Final Agency Action

A party aggrieved by a final action of the MHDO under these rules has the right to judicial review pursuant to 5 M.R.S.A., chapter 375, subchapter VII and M.R.Civ.P. 80(C). For purposes of this rule, the term "final agency action" means an action, or the failure or refusal to take a requested action, of or by the MHDO. Unless otherwise provided for by statute, an aggrieved party shall file a petition for judicial review of final agency action of the MHDO no later than thirty (30) business days after receipt of notice of MHDO action, or the failure or refusal of the MHDO to undertake a particular action.

STATUTORY AUTHORITY: 22 M.R.S.A. §8704, sub-§4 and §8707

EFFECTIVE DATE:
June 27, 1984

AMENDED:
October 5, 1987
April 24, 1991
November 5, 1991
July 6, 1994
January 1, 1995
February 17, 1998

NON-SUBSTANTIVE CORRECTION:
April 8, 1998 - insertion of “and” at the end of §2(C)(2)(b).

AMENDED:
February 13, 2000

NON-SUBSTANTIVE CORRECTIONS:
March 13, 2000

AMENDED:
August 9, 2003 - filing 2003-244, major substantive

NON-SUBSTANTIVE CORRECTIONS:
September 8, 2003 - removal of stray spaces

AMENDED:
August 6, 2005 – filing 2005-278
January 1, 2007 – filing 2006-209, major substantive
June 22, 2008 – filing 2008-227, major substantive
August 15, 2009 – filing 2009-366, major substantive